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# 1 Introduction

This document details the requirements of the functions implemented by the phases specific to communicating with a Distributed Control System (DCS). The phases are executed in the Production Execution Client of PharmaSuite.

In order to use the DCS phases, the following prerequisites apply:

- Rockwell Automation's DCS Adapter has to be installed and configured  
For details, please refer to "Functional Requirement Specification DCS Adapter" [A2] ([GID-2667776](#)) and "Technical Manual DCS Adapter" [A3] ([GID-2667776](#))
- A Distributed Control System has to be set up and configured. The alarms processed by the DCS phase are completely based on the alarms provided by the DCS.

Each requirement is composed of a name (e.g., Preview mode) and a unique identifier (e.g., GID-1234567) and is extended with its business attributes (GxP Relevance, Business Impact) and its compliance attribute (21 CFR Part 11 Relevance).

For requirements with **Framework capability** as identifier, see "Functional Requirement Specification Execution Framework" for their unique identifier, [A1] ([GID-2667776](#))

The revision history lists the changes made to the document with the previous FactoryTalk PharmaSuite release as the comparison baseline. It provides individual tables for "Updated", "Added", and "Deleted" requirements that juxtapose the previous approved version with the new approved version of an item.

## Typographical Conventions

This documentation uses typographical conventions to enhance the readability of the information it presents. The following kinds of formatting indicate specific information:

<b>Bold typeface</b>	Designates user interface texts, such as <ul style="list-style-type: none"><li>▪ window and dialog titles</li><li>▪ menu functions</li><li>▪ panel, tab, and button names</li><li>▪ box labels</li><li>▪ object properties and their values (e.g., status).</li></ul>
Monospaced typeface	Designates code examples.

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## 2 Automation Integration with DCS Phases

### 2.1 DCS Alarm-related Phases and Operations

The DCS alarm-related phases support different scenarios:

- Collecting alarms from the DCS at the end of the batch run  
To collect and annotate the alarms from the DCS, use the **Get DCS alarms** phase in a normal operation which is modeled after the DCS batch run is finished.
- Collecting alarms in parallel to normal processing  
To collect and annotate the alarms from the DCS as soon as they occur, we recommend to use event-triggered operations with the **DCS alarm-based trigger** phase.  
PharmaSuite for Production Execution uses event-triggered operations (ETOs) as templates to create specific runs (ETO instances), which then are executed by the operator.  
The creation of the runs is triggered either manually by an operator or automatically by a trigger phase. In the context of a Distributed Control System (DCS), this is done by the **DCS alarm-based trigger** phase.

The typical structure of a recipe with an event-triggered operation can be modeled with the following characteristics:

- An operation (**DCS Run**) with the **Event-triggered** capability represents an ETO.  
The runs can be created automatically by a trigger phase (**DCS alarm-based trigger**) if the operation also holds the **Trigger-enabled** capability.  
This operation contains the **Get DCS alarms** phase with the user interface to collect the alarms.
- For automatic triggers, the trigger phases are located in an operation (**DCS Triggers**) that holds the **Server-run** capability. Thus, the operation and its phases are not visible in the Production Execution Client.
- Both the **DCS Run** and the **DCS Triggers** operations are located on parallel branches, which means both operations become active during execution at the same time.
- The **Trigger-enabled** capability allows to reference specific trigger phases (**DCS alarm-based trigger**) that typically run on a server (within a server-run operation).  
One ETO can reference multiple trigger phases.  
One trigger phase can be referenced from multiple ETOs.

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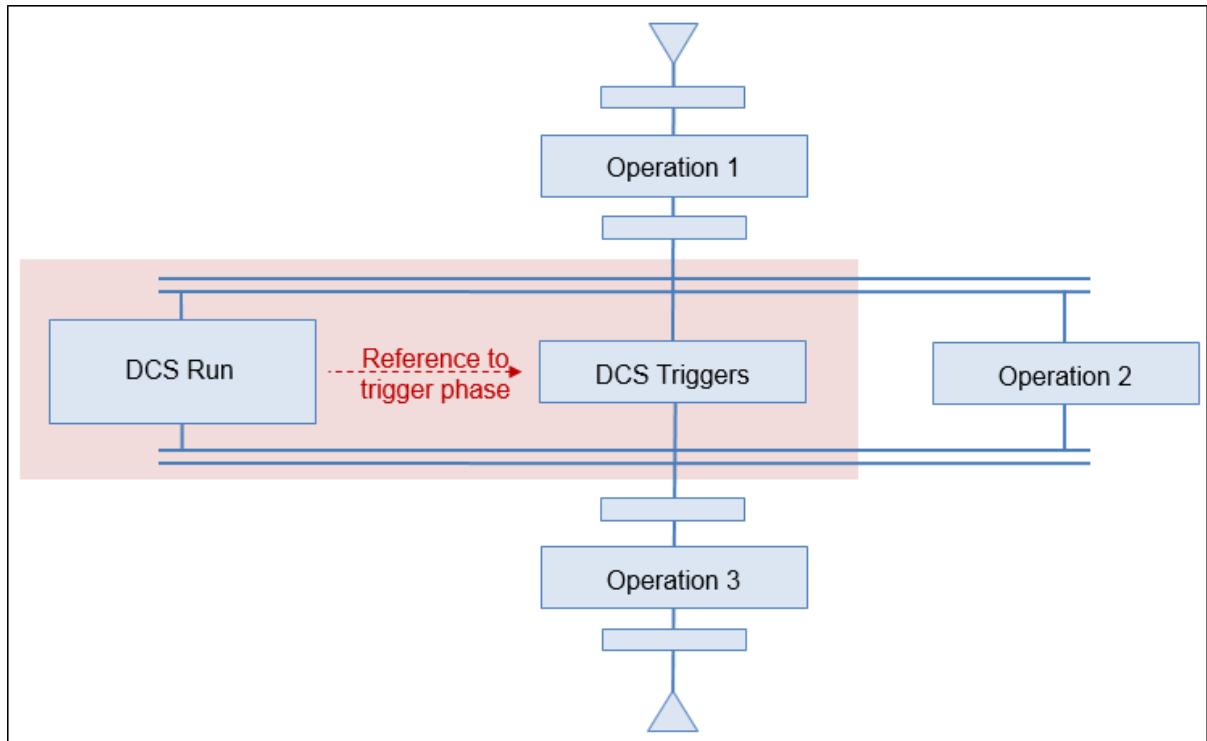


Figure 1: DCS-related phases and event-triggered operation within a recipe

### 2.1.1 Trigger Phases

The following trigger phases are available:

- DCS alarm-based trigger ([GID-2667685](#))

The **DCS alarm-based trigger** phase allows to automatically create runs of an event-triggered operation (ETO) based on DCS alarms whenever new DCS alarms are retrieved in the defined check cycle.

The phase is designed for being run on a server without user interaction.

The following rules apply with respect to start and completion of trigger processing of a trigger phase. For details, see **Business Logic (SR0510.2+)** of the DCS alarm-based trigger phase ([GID-2667685](#)).

- A trigger phase becomes active automatically according to SFC, but trigger processing does not start until at least one related ETO template has become active. That means that the template is visible in the Cockpit of all running Production Execution Clients, according to their station-level dispatching.
- If none of the related ETO templates becomes active, the trigger phase is completed automatically after its timeout period has elapsed.

- If trigger processing has started due to active ETO templates, the trigger phase is completed automatically as soon as there is no related ETO template active anymore. That means that the active ETO templates have been removed from the Cockpit by the operator.
- In case a unit procedure is paused by the operator, also the trigger processing of the trigger phases is paused. When the pause period of the unit procedure is ended by the operator, the trigger processing continues based on a new re-calculated trigger schedule.

## 2.2 Materials Management with Support of DCS Phases

In an automated and integrated environment, processing data needs to be exchanged between a DCS and PharmaSuite in order to document material balances that occurred in the DCS in the batch report of the product.

The **Set order context** phase ([GID-2667692](#)) ([GID-2667692](#)) downloads the context information of the current order to the DCS. Later on, material consumption and production data that is uploaded by the DCS is displayed by the **Show consumed material** phase ([GID-2667703](#)) and the **Show produced material** phase ([GID-2667714](#)). The operator can review the uploaded data and, if necessary, correct the data with user-triggered exceptions of the corresponding phases.

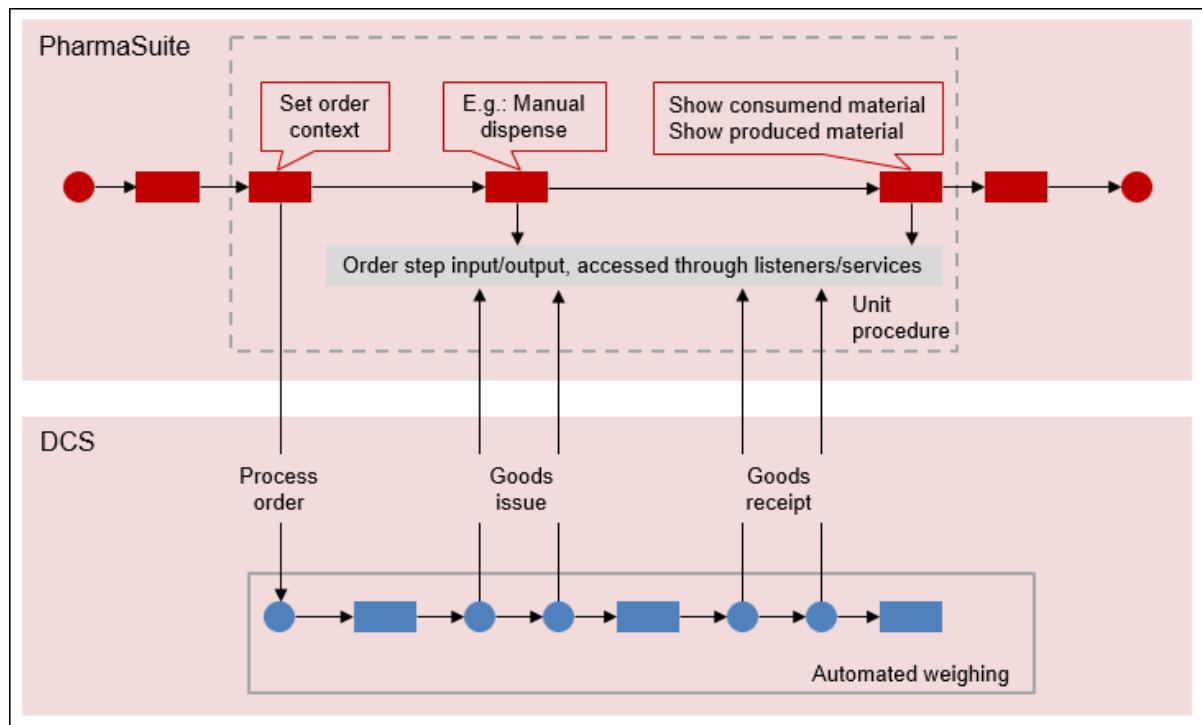


Figure 2: Use case for materials management

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## 2.3 Synchronization Between PharmaSuite Operations and a DCS

In an automated and integrated environment, processing data needs to be exchanged between a DCS and PharmaSuite in order to synchronize the processes between the systems.

The **Wait for event (OES)** phase ([GID-2667725](#)) receives an event message from the DCS, communicates with the **Send event** phase ([GID-2667743](#)), and thus synchronizes its **server-run operation** with the DCS. The phase must be used in a unit procedure together with the **Send event** phase which is configured to send an abort event in order to avoid that the completion of the unit procedure is blocked by the **Wait for event (OES)** phase.

Contrary to the server-run phase, the **Wait for event** phase ([GID-2667732](#)) is an operator-run phase and allows to synchronize its **operator-run operation** with the DCS.

In the asynchronous mode, it is not necessary that a targeted **Wait for event** phase is already running when the **Send event** phase or a DCS sends its request.

With the **Send event** phase ([GID-2667743](#)), running **Wait for event (OES)** phases can be aborted. Depending on the configuration, this applies to a specific **Wait for event (OES)** phase of the order or to all **Wait for event (OES)** phases of the common unit procedure.

Operator-run **Wait for event** phases provide a user-triggered exception for being aborted.

## 3 Create DCS Batch Phase (SR0520+)

The **Create DCS batch** phase allows an operator to request the creation of a batch on a DCS.

An example use case is:

- Creating a batch to be executed on an automation system  
Based on an existing master recipe and other product-specific parameters, the phase allows to create a DCS batch on a DCS.

Different phase modes enable the usage in various situations that can occur during processing:

- In the **Manual completion** mode, the operator manually triggers the creation of the batch.
- In the **Automatic completion** mode, the phase creates the batch and is completed automatically without any operator interaction.

The DCS, batch, master recipe, and further product-specific parameters are stored in the batch record, thereby becoming available for documentation purposes in the sub-report and batch report ([GID-2668660](#)).

Anomalies that occur during processing are covered by the phase exception handling ([GID-2667667](#)) (e.g. re-send creation request).

After completion the phase displays the created batch with its data in the Execution Window.

The Navigator displays the identifier of the created batch.

Create the batch on the DCS.			
DCS name:	JavaDCSMock	Batch ID:	BX57_V399
Master recipe ID:	ID_SRTD-100	Formula ID:	SR-100
Campaign ID:	2022-Q3	Scale:	100
Description:	Sonolin retard 100	<b>Create</b> 	
Unit class / step		Unit ID	
Automated Tablet Press/Tableting Run		U207-22	
Parameter		Value	UoM
Tablet Dimensions		9.0	mm
Tablet Form		Yes	
Status		OK	
Batch not created yet.			
		<b>Confirm</b> 	

Figure 3: Create DCS batch during execution

### 3.1 Layout

The phase provides individual layouts for its representation during execution ([GID-2668691](#)), in the Navigator ([GID-2668692](#)), and in the sub-report ([GID-2668693](#)).

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### **3.1.1 Representation during Execution (SR0520.1+)**

The representation during execution depends on the phase mode.

#### **3.1.1.1 GID-2670157 PREVIEW MODE (SR0520.1.1)**

1. <Instruction text>  
(taken from **Instruction (SR0520.8.1)** process parameter [\(GID-2670173\)](#))
2. DCS name: <logical name>  
Batch ID: <identifier>  
Master recipe ID: <identifier>  
Formula ID: <identifier>  
Campaign ID: <identifier>  
Scale: <value>  
Description: <text>  
(taken from **DCS (SR0520.8.3)** process parameter [\(GID-2670175\)](#) and **Definition (SR0520.8.4)** process parameter [\(GID-2670176\)](#))
3. List of up to 50 bundle parameters in the order of the bundle-specific process parameters:
  - **Boolean Value Bundle:**  
List of boolean value parameters  
(taken from the boolean value-specific **Master bundle identifier (SR0520.8.12)** process parameter [\(GID-2670183\)](#))
  - **Numeric Value Bundle:**  
List of numeric value parameters  
(taken from the numeric value-specific **Master bundle identifier (SR0520.8.13)** process parameter [\(GID-2670185\)](#))
  - **String Value Bundle:**  
List of string value parameters  
(taken from the string value-specific **Master bundle identifier (SR0520.8.11)** process parameter [\(GID-2670187\)](#))
  - **Unit Binding Bundle:**  
List of unit binding parameters  
(taken from the unit binding-specific **Master bundle identifier (SR0520.8.10)** process parameter [\(GID-2670189\)](#))
4. **Create** button (disabled).
5. **Confirm** button (disabled).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	Medium
MES-Compliance: 21 CFR Part 11 relevance	No

### 3.1.1.2 GID-2670158 ACTIVE MODE (SR0520.1.2)

1. Instruction table panel and/or instruction link panel  
(only if an instruction table and/or instruction link is defined for the phase)
  2. <Instruction text>  
(taken from **Instruction (SR0520.8.1)** process parameter ([GID-2670173](#)))
  3. DCS name: <logical name>  
Batch ID: <identifier>  
Master recipe ID: <identifier>  
Formula ID: <identifier>  
Campaign ID: <identifier>  
Scale: <value>  
Description: <text>  
(taken from **DCS (SR0520.8.3)** process parameter ([GID-2670175](#)) and **Definition (SR0520.8.4)** process parameter ([GID-2670176](#)))
  4. List of up to 50 bundle parameters in the order of the bundle-specific process parameters:
    - **Boolean Value Bundle:**  
List of boolean value parameters  
(taken from the boolean value-specific **Master bundle identifier (SR0520.8.12)** process parameter ([GID-2670183](#)))
    - **Numeric Value Bundle:**  
List of numeric value parameters  
(taken from the numeric value-specific **Master bundle identifier (SR0520.8.13)** process parameter ([GID-2670185](#)))
    - **String Value Bundle:**  
List of string value parameters  
(taken from the string value-specific **Master bundle identifier (SR0520.8.11)** process parameter ([GID-2670187](#)))
    - **Unit Binding Bundle:**  
List of unit binding parameters  
(taken from the unit binding-specific **Master bundle identifier (SR0520.8.10)** process parameter ([GID-2670189](#)))
- Batch creation-specific information:
- Batch not created yet.  
Initial message.
  - Batch created (<timestamp>): <batch ID>  
Batch has been created with the **Create** button or the **Re-send creation request (SR0520.3.1.2)** user-triggered exception ([GID-2670192](#)).
  - Batch created manually (<timestamp>): <batch ID>  
Batch has been created with the **Create batch manually (SR0520.3.1.1)** user-triggered

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exception [\(GID-2670190\)](#). If no batch identifier was specified, <batch ID> is DEFAULT\_BATCH\_ID.

- Batch creation failed.  
Batch could not be created with the **Create** button.
  - Batch re-creation failed.  
Batch could not be created with **Re-send creation request (SR0520.3.1.2)** user-triggered exception [\(GID-2670192\)](#).
5. **Create** button (disabled after a batch creation request has been sent).
  6. **Confirm** button.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

### 3.1.1.3 GID-2670159 COMPLETED MODE (SR0520.1.3)

1. Instruction table panel and/or instruction link panel  
(only if an instruction table and/or instruction link is defined for the phase)
2. <Instruction text>  
(taken from **Instruction (SR0520.8.1)** process parameter [\(GID-2670173\)](#))
3. DCS name: <logical name>  
Batch ID: <identifier>  
Master recipe ID: <identifier>  
Formula ID: <identifier>  
Campaign ID: <identifier>  
Scale: <value>  
Description: <text>  
(taken from **DCS (SR0520.8.3)** process parameter [\(GID-2670175\)](#) and **Definition (SR0520.8.4)** process parameter [\(GID-2670176\)](#))
4. List of up to 50 bundle parameters in the order of the bundle-specific process parameters:
  - **Boolean Value Bundle:**  
List of boolean value parameters  
(taken from the boolean value-specific **Master bundle identifier (SR0520.8.12)** process parameter [\(GID-2670183\)](#))
  - **Numeric Value Bundle:**  
List of numeric value parameters  
(taken from the numeric value-specific **Master bundle identifier (SR0520.8.13)** process parameter [\(GID-2670185\)](#))
  - **String Value Bundle:**  
List of string value parameters

(taken from the string value-specific **Master bundle identifier (SR0520.8.11)** process parameter ([GID-2670187](#)))

- **Unit Binding Bundle:**

List of unit binding parameters

(taken from the unit binding-specific **Master bundle identifier (SR0520.8.10)** process parameter ([GID-2670189](#)))

Batch creation-specific information:

- Batch created (<timestamp>): <batch ID>
- Batch created manually (<timestamp>): <batch ID>

5. **Create** button (disabled).

6. **Confirm** button (completed).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

### 3.1.2 Representation in Navigator (SR0520.4+)

The Navigator provides the following details:

#### 3.1.2.1 PHASE COLUMN (FRAMEWORK CAPABILITY)

- <Phase name>
  - Example:  
Create BS110 batch

#### 3.1.2.2 GID-2670161 INFORMATION COLUMN (SR0520.4.1)

- <Batch identifier>
  - Example: BX2859\_V15900

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	Medium
MES-Compliance: 21 CFR Part 11 relevance	No

#### 3.1.2.3 ACTION COLUMN

- There are no phase-specific actions available.

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### **3.1.3 Representation in Sub-report (SR0520.5+)**

The sub-report contains the following information:

#### **3.1.3.1 COMMON SUB-REPORT ELEMENTS (FRAMEWORK CAPABILITY)**

- <Start time>
- <Completion time>
- <Unit procedure> / <operation> / <phase>
- <Work center> / <station> / <device> - <phase completion user>

#### **3.1.3.2 GID-2670164 SUB-REPORT ELEMENTS (SR0520.5.1)**

- Instruction table panel and/or instruction link panel  
(only if an instruction table and/or instruction link is defined for the phase)
- Instruction text
- DCS name: <logical name>  
Batch ID: <identifier>  
Master recipe ID: <identifier>  
Formula ID: <identifier>  
Campaign ID: <identifier>  
Scale: <value>  
Description: <string>
- Table of unit binding bundle process parameters (in the order of the process parameters).
  - Unit class/step  
Unit ID
- Table of data type-specific bundle process parameters (in the order of the process parameters).
- Parameter  
Value  
UoM (only for numeric values)
- Table of created batches (in the order of their creation).
  - Batch ID  
Timestamp

In the grid, the phase displays "N/A" for those entries that cannot be provided due to their context (e.g. a unit of measure for a boolean value) or that have not been defined during recipe or workflow design (e.g. a lower limit for a numeric value).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

## 3.2 Business Logic (SR0520.2+)

The phase implements the following business logic.

### 3.2.1 Phase Mode

Business logic related to phase modes.

#### 3.2.1.1 GID-2670165 MANUAL COMPLETION MODE (SR0520.2.1)

- Function: **Manual completion** mode of phase
- Type: Phase mode
- Trigger: Phase becomes active
- Postcondition: Phase is active

Step	#	Description
Phase activation	10	Phase displays its user interface according to the <b>Active mode (SR0520.1.2)</b> layout ( <a href="#">GID-2670158</a> ).
Operator taps <b>Create</b> button	20	Phase creates the batch on the DCS, see <b>Create batch (SR0520.2.3)</b> function ( <a href="#">GID-2670167</a> ).
Phase completion	30	See <b>Confirm phase (SR0520.2.4)</b> function ( <a href="#">GID-2670168</a> ).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

#### 3.2.1.2 GID-2670166 AUTOMATIC COMPLETION MODE (SR0520.2.2)

- Function: **Automatic completion** mode of phase
- Type: Phase mode
- Trigger: Phase becomes active
- Postcondition: Phase is completed

Step	#	Description
Phase activation	10	Phase displays its user interface according to the <b>Active mode (SR0520.1.2)</b> layout ( <a href="#">GID-2670158</a> ).

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Step	#	Description
Phase creates batch	20	<p>See <b>Create batch (SR0520.2.3)</b> function (<a href="#">GID-2670167</a>).</p> <ul style="list-style-type: none"> <li>▪ If no error has occurred, continue with the <b>Confirm phase (SR0520.2.4)</b> function (<a href="#">GID-2670168</a>).</li> <li>▪ If an error has occurred, phase must be completed manually. See <b>Manual completion (SR0520.2.1)</b> mode (<a href="#">GID-2670165</a>).</li> </ul>

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

### 3.2.2 Main Path

Business logic related to the main path:

#### 3.2.2.1 GID-2670167 CREATE BATCH (SR0520.2.3)

- Function: Request batch creation
- Type: Main path
- Trigger: Operator creates batch or **Automatic completion (SR0520.2.2)** mode ([GID-2670166](#)) is active
- Postcondition: Phase is active

Step	#	Description
Phase creates batch	10	Phase creates the batch on the DCS and disables the <b>Create</b> button.
	20.1	<p>If an error has occurred, phase displays the <b>Batch creation error (SR0520.3.6.1)</b> error message (<a href="#">GID-2668674</a>). Continue with the <b>Re-send creation request (SR0520.3.1.2)</b> user-triggered exception (<a href="#">GID-2670192</a>) or the <b>Create batch manually (SR0520.3.1.1)</b> user-triggered exception (<a href="#">GID-2670190</a>).</p> <p>Phase can be completed with the <b>Confirm phase (SR0520.2.4)</b> function (<a href="#">GID-2670168</a>).</p>
	20.2	If no error has occurred, continue with the <b>Confirm phase (SR0520.2.4)</b> function ( <a href="#">GID-2670168</a> ).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

- Create DCS Batch Phase (SR0520+)
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### 3.2.2.2 GID-2670168 CONFIRM PHASE (SR0520.2.4)

- Function: Completion of phase
- Type: Main path
- Trigger: Operator confirms phase or **Automatic completion (SR0520.2.2)** mode ([GID-2670166](#)) is active
- Postcondition: Phase is completed

Step	#	Description
In Manual completion (SR0520.2.1) mode ( <a href="#">GID-2670165</a> ): Operator confirms phase	10	Operator confirms the creation of the batch.
Phase performs completion checks	20	If no batch has been created, phase displays the <b>No batch created (SR0520.3.6.2)</b> error message ( <a href="#">GID-2668675</a> ). The phase cannot be completed. Continue with the <b>Create batch manually (SR0520.3.1.1)</b> user-triggered exception ( <a href="#">GID-2670190</a> ).
Phase completion	30	Phase is completed.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

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### 3.3 Process Parameters (SR0520.8+)

The following process parameters define the behavior of the phase.

#### 3.3.1 *Instruction Table Specific Parameters*

##### 3.3.1.1 INSTRUCTION TABLE DEFINITION (FRAMEWORK CAPABILITY)

Attribute	Type	Comment
Table layout	Choice list	Defines the layout of the instruction table holding the instruction texts. Available settings: <b>1 column</b> , <b>2 columns</b> , <b>3 columns</b> , <b>4 columns</b> , <b>5 columns</b> . Default setting: <b>1 column</b> .
First column narrow	Boolean	Defines if the first column of the table shall be narrow.
Show all borders	Boolean	Defines if the borders of the table shall be visible.

##### 3.3.1.2 INSTRUCTION TABLE TEXT (FRAMEWORK CAPABILITY)

Attribute	Type	Comment
Column 1	HTML text	Instruction text to be displayed in a column.
Column 2	HTML text	<b>Restriction:</b> Maximum length is 2000 characters (including HTML tags).
Column 3	HTML text	
Column 4	HTML text	
Column 5	HTML text	

### 3.3.2 *Instruction Link-specific Parameters*

#### 3.3.2.1 INSTRUCTION TEXT WITH LINKS (FRAMEWORK CAPABILITY)

Attribute	Type	Comment
Instruction text	HTML text	<p>Instruction text to be displayed.</p> <p>For any text enclosed in curly brackets you can define a hyperlink with the <b>Instruction link definition</b> process parameter (<a href="#">GID-2670172</a>).</p> <p>Example: Refer to {SOP1270} for guidance.</p> <p>Maximum length is 2000 characters (including HTML tags).</p>

#### 3.3.2.2 INSTRUCTION LINK DEFINITION (FRAMEWORK CAPABILITY)

Attribute	Type	Comment
Link text	Text	<p>Text to be used as link.</p> <p>For any text enclosed in curly brackets within the instruction text you can define a link with the <b>Link URL</b> attribute.</p> <p>Including the brackets in the link text is optional.</p> <p>Maximum length is 80 characters.</p>
Link URL	Text	<p>URL of the file to be displayed. The link opens the external application assigned to the file type by the operating system.</p> <p>Maximum length is 256 characters.</p>

### 3.3.3 *Basic Parameters*

#### 3.3.3.1 GID-2670173 INSTRUCTION (SR0520.8.1)

Attribute	Type	Comment
Text	HTML text	<p>Instruction text to be displayed.</p> <p><b>Restriction:</b> Maximum length is 4000 characters (including HTML tags).</p>

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Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

### 3.3.3.2 GID-2670174 MODE (SR0520.8.2)

Attribute	Type	Comment
Mode	Choice list	Defines the processing mode. <b>Manual completion</b> (default): Operator confirms the phase. <b>Automatic completion</b> : Phase is automatically completed after a batch has been created successfully on the DCS.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

### 3.3.3.3 GID-2670175 DCS (SR0520.8.3)

Attribute	Type	Comment
Name	String	Logical name of the DCS to be used. The available entries correspond to the entries in the <b>DCSNames</b> list. Default setting: First entry in the list. Maximum length is 255 characters.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

- Create DCS Batch Phase (SR0520+)
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### 3.3.3.4 GID-2670176 DEFINITION (SR0520.8.4)

Attribute	Type	Comment
Batch ID	String	Defines the identifier of the batch to be created on the DCS. Maximum length is 250 characters. This attribute is required by the DCS Adapter.
Master recipe ID	String	Defines the identifier of the master recipe to be used. Maximum length is 200 characters. This attribute is required by the DCS Adapter.
Formula ID	String	Defines the identifier of the formula to be used. Maximum length is 200 characters.
Description	String	Defines the description of the batch to be created. Maximum length is 200 characters.
Campaign ID	String	Defines the identifier of the campaign to be used. Maximum length is 200 characters.
Scale	BigDecimal	Defines the scale of the batch in percent.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

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### **3.3.4 Configuration of User-triggered Exceptions**

#### **3.3.4.1 GID-2670177 CREATE BATCH MANUALLY (SR0520.8.5)**

Attribute	Type	Comment
Risk assessment	Choice list	Defines the risk level of the exception and thus controls the related signature privilege. Available settings: <b>None</b> , <b>Low</b> , <b>Low (mandatory comment)</b> , <b>Medium</b> , <b>Medium (mandatory comment)</b> , <b>High</b> , <b>High (mandatory comment)</b> . Default setting: <b>High</b> .
Exception text	Text	Defines the exception description used during exception handling and within the batch record. Maximum length is 250 characters.

See also Create batch manually (SR0520.3.1.1) user-triggered exception [\(GID-2670190\)](#).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

#### **3.3.4.2 GID-2670178 OVERRIDE DCS PARAMETER (SR0520.8.6)**

Attribute	Type	Comment
Risk assessment	Choice list	Defines the risk level of the exception and thus controls the related signature privilege. Available settings: <b>None</b> , <b>Low</b> , <b>Low (mandatory comment)</b> , <b>Medium</b> , <b>Medium (mandatory comment)</b> , <b>High</b> , <b>High (mandatory comment)</b> . Default setting: <b>High</b> .
Exception text	Text	Defines the exception description used during exception handling and within the batch record. Maximum length is 250 characters.

- Create DCS Batch Phase (SR0520+)
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See also **Override DCS parameter (SR0520.3.1.3)** user-triggered exception ([GID-2670194](#)).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

### 3.3.4.3 GID-2670179 OVERRIDE BUNDLE PARAMETER (SR0520.8.7)

Attribute	Type	Comment
Risk assessment	Choice list	Defines the risk level of the exception and thus controls the related signature privilege. Available settings: <b>None</b> , <b>Low</b> , <b>Low (mandatory comment)</b> , <b>Medium</b> , <b>Medium (mandatory comment)</b> , <b>High</b> , <b>High (mandatory comment)</b> . Default setting: <b>High</b> .
Exception text	Text	Defines the exception description used during exception handling and within the batch record. Maximum length is 250 characters.

See also **Override bundle parameter (String value) (SR0520.3.1.5)** user-triggered exception ([GID-2671661](#)), **Override bundle parameter (Boolean value) (SR0520.3.1.6)** user-triggered exception ([GID-2671657](#)), and **Override bundle parameter (Numeric value) (SR0520.3.1.7)** user-triggered exception ([GID-2671659](#)).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

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### 3.3.4.4 GID-2670180 OVERRIDE UNIT BINDING (SR0520.8.8)

Attribute	Type	Comment
Risk assessment	Choice list	Defines the risk level of the exception and thus controls the related signature privilege. Available settings: <b>None</b> , <b>Low</b> , <b>Low (mandatory comment)</b> , <b>Medium</b> , <b>Medium (mandatory comment)</b> , <b>High</b> , <b>High (mandatory comment)</b> . Default setting: <b>High</b> .
Exception text	Text	Defines the exception description used during exception handling and within the batch record. Maximum length is 250 characters.

See also **Override unit binding (SR0520.3.1.4)** user-triggered exception ([GID-2671663](#)).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

### 3.3.4.5 GID-2670181 RE-SEND CREATION REQUEST (SR0520.8.9)

Attribute	Type	Comment
Risk assessment	Choice list	Defines the risk level of the exception and thus controls the related signature privilege. Available settings: <b>None</b> , <b>Low</b> , <b>Low (mandatory comment)</b> , <b>Medium</b> , <b>Medium (mandatory comment)</b> , <b>High</b> , <b>High (mandatory comment)</b> . Default setting: <b>High</b> .
Exception text	Text	Defines the exception description used during exception handling and within the batch record. Maximum length is 250 characters.

See also **Re-send creation request (SR0520.3.1.2)** user-triggered exception ([GID-2670192](#)).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

### 3.3.5 Boolean Value Bundle

#### 3.3.5.1 [BOOLEAN] BUNDLE PROCESS PARAMETERS (FRAMEWORK CAPABILITY)

For the master process parameter of a bundle, its internal identifier is populated from the bundle identifier.

For all other process parameters of the bundle, their internal identifier is a concatenation of the bundle identifier and the process parameter name.

This framework capability refers to **Bundle Process Parameters (SR3146.9.7.4.1)** in "Functional Requirement Specification Recipe and Workflow Management" [A4] ([GID-2667776](#)).

#### 3.3.5.2 GID-2670183 [BOOLEAN] MASTER (BUNDLE IDENTIFIER) (SR0520.8.12)

Attribute	Type	Comment
Parameter	String	Defines the identifier of the parameter to be used. Maximum length is 200 characters.
Value	Boolean	Defines the value of the parameter.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

### 3.3.6 Numeric Value Bundle

#### 3.3.6.1 [NUMERIC] BUNDLE PROCESS PARAMETERS (FRAMEWORK CAPABILITY)

For the master process parameter of a bundle, its internal identifier is populated from the bundle identifier.

For all other process parameters of the bundle, their internal identifier is a concatenation of the bundle identifier and the process parameter name.

This framework capability refers to **Bundle Process Parameters (SR3146.9.7.4.1)** in "Functional Requirement Specification Recipe and Workflow Management" [A4] ([GID-2667776](#)).

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### 3.3.6.2 GID-2670185 [NUMERIC] MASTER (BUNDLE IDENTIFIER) (SR0520.8.13)

Attribute	Type	Comment
Parameter	String	Defines the identifier of the parameter to be used. Maximum length is 200 characters.
Value	BigDecimal	Defines the value of the parameter.
UoM	Unit of measure	Must match a unit of measure available within PharmaSuite.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

### 3.3.7 String Value Bundle

#### 3.3.7.1 [STRING] BUNDLE PROCESS PARAMETERS (FRAMEWORK CAPABILITY)

For the master process parameter of a bundle, its internal identifier is populated from the bundle identifier.

For all other process parameters of the bundle, their internal identifier is a concatenation of the bundle identifier and the process parameter name.

This framework capability refers to **Bundle Process Parameters (SR3146.9.7.4.1)** in "Functional Requirement Specification Recipe and Workflow Management" [A4] ([GID-2667776](#))

#### 3.3.7.2 GID-2670187 [STRING] MASTER (BUNDLE IDENTIFIER) (SR0520.8.11)

Attribute	Type	Comment
Parameter	String	Defines the identifier of the parameter to be used. Maximum length is 200 characters.
Value	String	Defines the value of the parameter. Maximum length is 200 characters.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

### 3.3.8 Unit Binding Bundle

#### 3.3.8.1 [UNIT BINDING] BUNDLE PROCESS PARAMETERS (FRAMEWORK CAPABILITY)

For the master process parameter of a bundle, its internal identifier is populated from the bundle identifier.

For all other process parameters of the bundle, their internal identifier is a concatenation of the bundle identifier and the process parameter name.

This framework capability refers to **Bundle Process Parameters (SR3146.9.7.4.1)** in "Functional Requirement Specification Recipe and Workflow Management" [A4] ([GID-2667776](#))

#### 3.3.8.2 GID-2670189 [UNIT BINDING] MASTER (BUNDLE IDENTIFIER) (SR0520.8.10)

Attribute	Type	Comment
Unit class/step	String	Defines the required unit class or step. Maximum length is 200 characters.
Unit ID	String	Defines the identifier of the unit to be used. Maximum length is 200 characters.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

### 3.4 Exceptions (SR0520.3+)

The phase supports user-defined, user-triggered ([GID-2668672](#)), system-triggered ([GID-2668671](#)), and post-completion exceptions ([GID-2668673](#)) and their configuration by means of process parameters ([GID-2667666](#)).

User-defined exceptions cannot be configured by process parameters since they are provided by the framework and independent of phases.

#### 3.4.1 System-triggered Exceptions

There are no system-triggered exceptions available.

#### 3.4.2 User-triggered Exceptions (SR0520.3.1+)

A user-triggered exception is represented in the list of available user-triggered exceptions in the Exception Window, as the description of the exception, and in the batch report.

The following user-triggered exceptions are available.

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### 3.4.2.1 GID-2670190 CREATE BATCH MANUALLY (SR0520.3.1.1)

The **Create batch manually** exception allows an operator to create the DCS batch manually based on the internal batch identifier of the DCS batch. If the identifier is unknown, the phase uses DEFAULT\_BATCH\_ID as batch identifier to create the DCS batch on the DCS. With the exception, the phase overrides the recently created batch, if available.

Representation of the exception:

- Instruction:  
Create the DCS batch manually.  
Batch ID <value>  
**Confirm** button.
- Exception text:  
<Exception text>  
(taken from **Create batch manually (SR0520.8.5)** process parameter ([GID-2670177](#)))  
Manual entry: < batch identifier>  
If no batch identifier was specified:  
Manual entry: N/A (DEFAULT\_BATCH\_ID)
  - Example:  
Batch created manually  
Manual entry: BS101338\_04Jul2016\_2111\_PV51400

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

### 3.4.2.2 GID-2670191 CREATE BATCH MANUALLY - LOGIC (SR0520.3.1.1.1)

- Trigger: Exception is selected
- Postcondition: DCS batch is created on the DCS

Step	#	Description
Operator confirms and signs exception	10	Phase records the exception, updates batch creation-specific information in the <b>Active mode (SR0520.1.2)</b> layout ( <a href="#">GID-2670158</a> ), and disables the <b>Create</b> button in the <b>Active mode (SR0520.1.2)</b> layout ( <a href="#">GID-2670158</a> ).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

- Create DCS Batch Phase (SR0520+)
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### 3.4.2.3 GID-2670192 RE-SEND CREATION REQUEST (SR0520.3.1.2)

The **Re-send creation request** exception allows an operator to re-send the DCS batch creation request to the DCS.

With the exception, the phase overrides the recently created batch, if available.

Representation of the exception:

- Instruction:  
Re-send the DCS batch creation request.  
**Confirm** button.
- Exception text:  
<Exception text>  
(taken from **Re-send creation request (SR0520.8.9)** process parameter ([GID-2670181](#)))  
Batch ID: <value>
- Example:  
Batch creation repeated.  
Batch ID: BX2859\_V15900

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

### 3.4.2.4 GID-2670193 RE-SEND CREATION REQUEST - LOGIC (SR0520.3.1.2.1)

- Trigger: Exception is selected
- Postcondition: DCS batch is created on the DCS

Step	#	Description
Operator confirms and signs exception	10	Phase records the exception and sends a creation request to the DCS.
Phase receives feedback from the DCS	20	Phase adds a comment with the batch creation result <ul style="list-style-type: none"> <li>▪ Batch created (&lt;timestamp&gt;): &lt;batch ID&gt;</li> <li>▪ Batch re-creation failed</li> </ul> to the exception, updates batch creation-specific information in the <b>Active mode (SR0520.1.2)</b> layout ( <a href="#">GID-2670158</a> ), and disables the <b>Create</b> button in the <b>Active mode (SR0520.1.2)</b> layout ( <a href="#">GID-2670158</a> ). If the batch re-creation fails, the phase cannot be completed (see <b>Confirm phase (SR0520.2.4)</b> function ( <a href="#">GID-2670168</a> )).

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Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

### 3.4.2.5 GID-2670194 OVERRIDE DCS PARAMETER (SR0520.3.1.3)

The **Override DCS parameter** exception allows an operator to override the DCS parameters defined in the master recipe/workflow.

Representation of the exception:

- Instruction:  
Override a defined DCS parameter.  
Batch ID:  
Current value <value>  
New value <value>  
Master recipe ID:  
Current value <value>  
New value <value>  
Formula ID:  
Current value <value>  
New value <value>  
Campaign ID:  
Current value <value>  
New value <value>  
Scale:  
Current value <value>  
New value <value>  
Description:  
Current value <value>  
New value <value>  
**Confirm** button.
- Exception text:  
<Exception text>  
(taken from **Override DCS parameter (SR0520.8.6)** process parameter ([GID-2670178](#)))  
Batch ID:  
Old value: <old value>  
New value: <new value>  
Master recipe ID:  
Old value: <old value>  
New value: <new value>  
▪ Example:  
Parameter overridden.  
Batch ID:

Old value: BX2859\_V15901  
 New value: BX2859\_V15900  
 Master recipe ID:  
 Old value: ID\_SRTD\_002  
 New value: ID\_SRTD\_001

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

#### 3.4.2.6 GID-2670195 OVERRIDE DCS PARAMETER - LOGIC (SR0520.3.1.3.1)

- Trigger: Exception is selected
- Postcondition: Value of DCS parameter is overridden

Step	#	Description
Operator confirms and signs exception	10	Phase records the exception.
Operator interaction	20	Operator taps <b>Create</b> button in the <b>Active mode</b> (SR0520.1.2) layout ( <a href="#">GID-2670158</a> ) or triggers the <b>Re-send creation request</b> (SR0520.3.1.2) user-triggered exception ( <a href="#">GID-2670192</a> ) to create a DCS batch with the new values.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

#### 3.4.2.7 BOOLEAN VALUE BUNDLE

##### 3.4.2.7.1 GID-2671657 OVERRIDE BUNDLE PARAMETER (SR0520.3.1.6)

The **Override bundle parameter** exception allows an operator to override the values of a boolean value-specific process parameter defined in the master recipe/workflow.

There is one exception per boolean value-specific process parameter.

Representation during exception handling:

- Instruction:  
 <Parameter>  
 (taken from the boolean-specific **Master (bundle identifier)** (SR0520.8.12) process parameter ([GID-2670183](#)))  
 Override the defined value:  
 Current value <value>

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New value <value>

**Confirm** button.

- Exception text:  
<Exception text>  
(taken from **Override bundle parameter (SR0520.8.7)** process parameter ([GID-2670179](#)))  
<Parameter>  
(taken from the boolean-specific **Master (bundle identifier) (SR0520.8.12)** process parameter ([GID-2670183](#)))  
Old value: <value>  
New value: <value>
- Example:  
Parameter overridden.  
Pressure indicator active  
Old value: No  
New value: Yes

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

#### 3.4.2.7.2 GID-2671658 OVERRIDE BUNDLE PARAMETER - LOGIC (SR0520.3.1.6.1)

- Trigger: Exception is selected
- Postcondition: Value of bundle parameter is overridden

Step	#	Description
Operator confirms and signs exception	10	Phase records the exception. Additionally, phase adds the exception marker to the value's cell in the <b>Active mode (SR0520.1.2)</b> layout ( <a href="#">GID-2670158</a> ).
Operator interaction	20	Operator taps <b>Create</b> button in the <b>Active mode (SR0520.1.2)</b> layout ( <a href="#">GID-2670158</a> ) or triggers the <b>Re-send creation request (SR0520.3.1.2)</b> user-triggered exception ( <a href="#">GID-2670192</a> ) to create a DCS batch with the new values.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

### 3.4.2.8 NUMERIC VALUE BUNDLE

#### 3.4.2.8.1 GID-2671659 OVERRIDE BUNDLE PARAMETER (SR0520.3.1.7)

The **Override bundle parameter** exception allows an operator to override the values of a numeric value-specific process parameter defined in the master recipe/workflow.

There is one exception per numeric value-specific process parameter.

Representation during exception handling:

- Instruction:  
`<Parameter>`  
 (taken from the numeric-specific **Master (bundle identifier) (SR0520.8.13)** process parameter ([GID-2670185](#)))  
 Override the defined value:  
 Current value <value> <unit of measure>  
 New value <value> <unit of measure>  
**Confirm** button.
- Exception text:  
`<Exception text>`  
 (taken from **Override bundle parameter (SR0520.8.7)** process parameter ([GID-2670179](#)))  
`<Parameter>`  
 (taken from the numeric-specific **Master (bundle identifier) (SR0520.8.13)** process parameter ([GID-2670185](#)))  
 Old value: <value> <unit of measure>  
 New value: <value> <unit of measure>
- Example:  
 Parameter overridden.  
 Table size  
 Old value: 7.8 mm  
 New value: 7.9 mm

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

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### 3.4.2.8.2 GID-2671660 OVERRIDE BUNDLE PARAMETER - LOGIC (SR0520.3.1.7.1)

- Trigger: Exception is selected
- Postcondition: Value of bundle parameter is overridden

Step	#	Description
Operator confirms and signs exception	10	Phase records the exception. Additionally, phase adds the exception marker to the value's cell in the <b>Active mode (SR0520.1.2)</b> layout ( <a href="#">GID-2670158</a> ).
Operator interaction	20	Operator taps <b>Create</b> button in the <b>Active mode (SR0520.1.2)</b> layout ( <a href="#">GID-2670158</a> ) or triggers the <b>Re-send creation request (SR0520.3.1.2)</b> user-triggered exception ( <a href="#">GID-2670192</a> ) to create a DCS batch with the new values.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

### 3.4.2.9 STRING VALUE BUNDLE

#### 3.4.2.9.1 GID-2671661 OVERRIDE BUNDLE PARAMETER (SR0520.3.1.5)

The **Override bundle parameter** exception allows an operator to override the values of a string value-specific process parameter defined in the master recipe/workflow.

There is one exception per string value-specific process parameter.

Representation during exception handling:

- Instruction:  
`<Parameter>`  
(taken from the numeric-specific **Master (bundle identifier) (SR0520.8.13)** process parameter ([GID-2670185](#)))  
Override the defined value:  
Current value `<value>`  
New value `<value>`  
**Confirm** button.
- Exception text:  
`<Exception text>`  
(taken from **Override bundle parameter (SR0520.8.7)** process parameter ([GID-2670179](#)))  
`<Parameter>`  
(taken from the numeric-specific **Master (bundle identifier) (SR0520.8.13)** process parameter ([GID-2670185](#)))  
Old value: `<value>`  
New value: `<value>`

- Example:  
Parameter overridden.  
Target batch ID  
Old value: BX40060  
New value: BX40061

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

#### 3.4.2.9.2 GID-2671662 OVERRIDE BUNDLE PARAMETER - LOGIC (SR0520.3.1.5.1)

- Trigger: Exception is selected
- Postcondition: Value of bundle parameter is overridden

Step	#	Description
Operator confirms and signs exception	10	Phase records the exception. Additionally, phase adds the exception marker to the value's cell in the <b>Active mode (SR0520.1.2)</b> layout ( <a href="#">GID-2670158</a> ).
Operator interaction	20	Operator taps <b>Create</b> button in the <b>Active mode (SR0520.1.2)</b> layout ( <a href="#">GID-2670158</a> ) or triggers the <b>Re-send creation request (SR0520.3.1.2)</b> user-triggered exception ( <a href="#">GID-2670192</a> ) to create a DCS batch with the new values.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

#### 3.4.2.10 UNIT BINDING BUNDLE

##### 3.4.2.10.1 GID-2671663 OVERRIDE UNIT BINDING (SR0520.3.1.4)

The **Override unit binding** exception allows an operator to override the unit identifiers of the unit binding-specific process parameter defined in the master recipe/workflow.

There is one exception per unit binding-specific process parameter.

Representation during exception handling:

- Instruction:  
Override the defined unit binding:  
<Unit class/step>  
(unit binding-specific **Master (bundle identifier) (SR0520.8.10)** process parameter ([GID-2670189](#)))  
Current unit ID <value>

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New unit ID <value>

**Confirm** button.

- Exception text:  
<Exception text>  
(taken from **Override unit binding (SR0520.8.8)** process parameter ([GID-2670180](#)))  
<Unit class/step>  
(unit binding-specific **Master (bundle identifier) (SR0520.8.10)** process parameter ([GID-2670189](#)))  
Old unit ID: <value>  
New unit ID: <value>
- Example:  
Unit binding overridden.  
Step 1  
Old unit ID: U207-22-067  
New unit ID: U207-22-06

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

#### 3.4.2.10.2 GID-2671664 OVERRIDE UNIT BINDING - LOGIC (SR0520.3.1.4.1)

Trigger: Exception is selected

Postcondition: Value of unit binding parameter is overridden

Step	#	Description
Operator confirms and signs exception	10	Phase records the exception. Additionally, phase adds the exception marker to the value's cell in the <b>Active mode (SR0520.1.2)</b> layout ( <a href="#">GID-2670158</a> ).
Operator interaction	20	Operator taps <b>Create</b> button in the <b>Active mode (SR0520.1.2)</b> layout ( <a href="#">GID-2670158</a> ) or triggers the <b>Re-send creation request (SR0520.3.1.2)</b> user-triggered exception ( <a href="#">GID-2670192</a> ) to create a DCS batch with the new values.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

#### 3.4.3 Post-completion Exceptions

There are no post-completion exceptions available.

### 3.5 Information Messages

There are no information messages available.

### 3.6 Questions

There are no questions available.

### 3.7 Decisions

There are no decisions available.

### 3.8 Error Messages (SR0520.3.6+)

Error messages are represented in an error message dialog containing a message type-specific icon, the error message, and an **OK** button.

The following error messages are available to inform the operator about error conditions.

#### 3.8.1 *GID-2668674 Batch creation error (SR0520.3.6.1)*

UI text	Comment
Cannot create the batch on the DCS.	Message pack: PhaseCreateDCSBatch<version> Message ID: BatchCreateError_message

The **Details** button provides access to more specific technical information.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

#### 3.8.2 *GID-2668675 No batch created (SR0520.3.6.2)*

UI text	Comment
You have to create a batch before you can confirm.	Message pack: PhaseCreateDCSBatch<version> Message ID: NoBatchCreated_ErrorMsg

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

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## 3.9 Output Variables (SR0520.9+)

The following output variables are available to reference the phase's output.

### 3.9.1 *Instance count (Framework capability)*

- Data type: Long
- Usage: The output variable provides the count of the number of instances the phase has been processed, for example in a loop. The count is also increased when the phase is skipped from an operator's perspective, since the phase is still executed, but as a hidden phase.  
The count variable of a phase that has not been executed provides 0 as output value.

### 3.9.2 *Start time (Framework capability)*

- Data type: Timestamp
- Usage: The output variable provides the start time of the phase.

### 3.9.3 *Completion time (Framework capability)*

- Data type: Timestamp
- Usage: The output variable provides the completion time of the phase.

### 3.9.4 *Identifier (Framework capability)*

- Data type: String
- Usage: The output variable provides the identifier of the phase.

### 3.9.5 *GID-2668680 Batch ID (SR0520.9.1)*

- Data type: String
- Usage: The output variable provides the identifier of the DCS batch that was created on the DCS.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

### 3.9.6 *GID-3083043 Internal batch ID (SR0520.9.2)*

- Data type: String
- Usage: The output variable provides the identifier of the internal batch that depends on the used DCS.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

### **3.9.7 GID-2668681 Master recipe ID (SR0520.9.3)**

- Data type: String
- Usage: The output variable provides the identifier of the master recipe that was used to create the DCS batch.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

### **3.9.8 GID-2668682 Formula ID (SR0520.9.4)**

- Data type: String
- Usage: The output variable provides the identifier of the formula that was used to create the DCS batch.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

### **3.9.9 GID-2668683 Campaign ID (SR0520.9.5)**

- Data type: String
- Usage: The output variable provides the identifier of the campaign that was used to create the DCS batch.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

### **3.9.10 GID-2668684 Scale (SR0520.9.6)**

- Data type: BigDecimal
- Usage: The output variable provides the scale that was used to create the DCS batch.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

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### **3.9.11 Boolean Value Bundle**

#### **3.9.11.1 [BOOLEAN] BUNDLE OUTPUT VARIABLE (FRAMEWORK CAPABILITY)**

For all output variables of the same bundle, the output variable identifier is a concatenation of the bundle identifier and the output variable name.

This framework capability refers to **Bundle Output Variable (SR3146.9.7.4.2)** in "Functional Requirement Specification Recipe and Workflow Management" [A4] ([GID-2667776](#)) ([GID-2667776](#))

#### **3.9.11.2 GID-2670201 [BOOLEAN] PARAMETER (SR0520.9.11)**

- Data type: String
- Usage: The output variable provides the identifier of the parameter that was used to create the DCS batch.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

#### **3.9.11.3 GID-2670202 [BOOLEAN] VALUE (SR0520.9.12)**

- Data type: Boolean
- Usage: The output variable provides the value of the parameter that was used to create the DCS batch.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

### **3.9.12 Numeric Value Bundle**

[Numeric] Bundle output variable (Framework capability)

For all output variables of the same bundle, the output variable identifier is a concatenation of the bundle identifier and the output variable name.

This framework capability refers to **Bundle Output Variable (SR3146.9.7.4.2)** in "Functional Requirement Specification Recipe and Workflow Management" [A4] ([GID-2667776](#))

#### **3.9.12.1 GID-2670203 [NUMERIC] PARAMETER (SR0520.9.13)**

- Data type: String
- Usage: The output variable provides the identifier of the parameter that was used to create the DCS batch.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

### 3.9.12.2 GID-2670204 [NUMERIC] VALUE (SR0520.9.14)

- Data type: BigDecimal
- Usage: The output variable provides the value of the parameter that was used to create the DCS batch.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

### 3.9.12.3 GID-2670205 [NUMERIC] UNIT OF MEASURE (SR0520.9.15)

- Data type: String
- Usage: The output variable provides the unit of measure of the parameter that was used to create the DCS batch.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

## 3.9.13 String Value Bundle

### 3.9.13.1 [STRING] BUNDLE OUTPUT VARIABLE (FRAMEWORK CAPABILITY)

For all output variables of the same bundle, the output variable identifier is a concatenation of the bundle identifier and the output variable name.

This framework capability refers to **Bundle Output Variable (SR3146.9.7.4.2)** in "Functional Requirement Specification Recipe and Workflow Management" [A4] ([GID-2667776](#)).

### 3.9.13.2 GID-2670207 [STRING] PARAMETER (SR0520.9.9)

- Data type: String
- Usage: The output variable provides the identifier of the parameter that was used to create the DCS batch.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

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### 3.9.13.3 GID-2670208 [STRING] VALUE (SR0520.9.10)

- Data type: String
- Usage: The output variable provides the value of the parameter that was used to create the DCS batch.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

### 3.9.14 Unit Binding Bundle

#### 3.9.14.1 [UNIT BINDING] BUNDLE OUTPUT VARIABLE (FRAMEWORK CAPABILITY)

For all output variables of the same bundle, the output variable identifier is a concatenation of the bundle identifier and the output variable name.

This framework capability refers to **Bundle Output Variable (SR3146.9.7.4.2)** in "Functional Requirement Specification Recipe and Workflow Management" [A4] ([GID-2667776](#))

#### 3.9.14.2 GID-2670210 [UNIT BINDING] UNIT CLASS (SR0520.9.7)

- Data type: String
- Usage: The output variable provides the unit class that was used to create the DCS batch.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

#### 3.9.14.3 GID-2670211 [UNIT BINDING] UNIT ID (SR0520.9.8)

- Data type: String
- Usage: The output variable provides the identifier of the unit that was used to create the DCS batch.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

### 3.10 Configuration Keys (SR0520.11+)

The following configuration keys are available to configure the phase's behavior.

#### 3.10.1 *GID-2668689 Message broker URL (SR0520.11.1)*

- Phase/DCS/DCSMessagingBrokerURL
- **Type:** String
- **Value:** tcp://<hostname>:<port>
- **Description:** Specifies the URL of the messaging server used for DCS communication. Replace <hostname> with the name of the host to be used and <port> with the port number of the host to be used.  
If no value is set, the URL defined in the PharmaSuite **MessageBrokerURL** configuration key is used.
- **Evaluated:** When a DCS phase communicates with a DCS.
- **Range:** N/A

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

#### 3.10.2 *GID-2668690 Messaging timeout (SR0520.11.2)*

- Phase/DCS/DCSMessagingTimeout
- **Type:** Long
- **Value:** 2
- **Description:** The messaging timeout for DCS communication in seconds and the time how long a produced DCS message shall be retained by the messaging system after it has been dispatched.  
If no value is set, the timeout defined in the PharmaSuite **MessagingTimeout** configuration key is used (converted into seconds).
- **Evaluated:** When a DCS phase communicates with a DCS.
- **Range:** N/A

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

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## 4 Get DCS Alarms Phase (SR0500+)

The **Get DCS alarms** phase allows an operator to request alarm-specific data from a batch running on a DCS.

Example use cases are:

- Concurrent retrieval of alarms for recording in the batch report  
Alarms on the DCS are retrieved every five minutes. In case an alarm has occurred, the alarm can be converted into an exception. Then it is documented in the batch report and included in the review and approval process.
- Retrieval of alarms after completion of a batch run for recording in the batch report  
After a batch run has been completed, all alarms that have occurred during the run are retrieved and converted into exceptions. They are documented in the batch report and included in the review and approval process.

The batch, unit, alarm timeframe, modules, and the alarms with their details are stored in the batch record, thereby becoming available for documentation purposes in the sub-report and batch report ([GID-2668693](#)).

Anomalies that occur during processing are covered by the phase exception handling ([GID-2668704](#)) (e.g. unconverted alarms).

After completion the phase displays the number of retrieved alarms in the Execution Window.

The Navigator displays the number of retrieved alarms.

Convert alarms to exceptions.

DCS name: JavaDCSMock	Batch ID: BX57_V399
Unit ID: U207-22	Modules: N/A
Start: 09/28/2022 12:38:10 PM IST	
End: 09/29/2022 12:00:00 AM IST	

Get Exception

	Timestamp	Source	Alarm	Comment
<input checked="" type="checkbox"/>	09/28/2022 12:44:14 PM IST		Attr: LO_ALM Word: LOW Level: 10-WARNING Desc: Low Alarm Value 64.79 Limit 65	
<input checked="" type="checkbox"/>	09/28/2022 12:44:05 PM IST		Attr: LO_ALM Word: LOW Level: 10-WARNING Desc: Low Alarm Value 64.11 Limit 65	
<input checked="" type="checkbox"/>	09/28/2022 12:43:52 PM IST		Attr: LO_ALM Word: LOW Level: 15-CRITICAL Desc: Low Alarm Value 61.37 Limit 65	Adjusted pressure at valve7
<input checked="" type="checkbox"/>	09/28/2022 12:43:35 PM IST		Attr: LO_ALM Word: LOW Level: 15-CRITICAL Desc: Low Alarm Value 60.46 Limit 65	Adjusted pressure at valve5

Last update completed (09/28/2022 12:44:18 PM IST) Confirm

Figure 4: Get DCS alarms during execution

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## 4.1 Layout

The phase provides individual layouts for its representation during execution ([\(GID-2668691\)](#), in the Navigator ([\(GID-2668692\)](#), and in the sub-report ([\(GID-2668693\)](#).

### 4.1.1 Representation during Execution (SR0500.1+)

The representation during execution depends on the phase mode.

#### 4.1.1.1 GID-2670212 PREVIEW MODE (SR0500.1.1)

1. <Instruction text>  
(taken from **Instruction (SR0500.8.1)** process parameter ([\(GID-2670224\)](#))
2. Start: <timestamp>  
End: <timestamp>
3. DCS name: <logical name>  
Batch ID: <identifier> Unit ID: <identifier>  
Modules: <list of identifiers>  
(taken from **DCS (SR0500.8.2)** process parameter ([\(GID-2670225\)](#) and **Filter criteria (SR0500.8.3)** process parameter ([\(GID-2670226\)](#))
4. **Get** button (disabled).
5. **Exception** button (disabled).
6. List of alarms
7. Update-related information:
  - Time of last update unknown  
No manual or automatic update has been performed yet.
8. **Confirm** button (disabled).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	Medium
MES-Compliance: 21 CFR Part 11 relevance	No

#### 4.1.1.2 GID-2670213 ACTIVE MODE (SR0500.1.2)

1. Instruction table panel and/or instruction link panel  
(only if an instruction table and/or instruction link is defined for the phase)
2. <Instruction text>  
(taken from **Instruction (SR0500.8.1)** process parameter ([\(GID-2670224\)](#))
3. Start: <timestamp>  
End: <timestamp>

4. DCS name: <logical name>  
Batch ID: <identifier> Unit ID: <identifier>  
Modules: <list of identifiers>  
(taken from **DCS (SR0500.8.2)** process parameter ([GID-2670225](#)) and **Filter criteria (SR0500.8.3)** process parameter ([GID-2670226](#)))
5. **Get** button.
6. **Exception** button (disabled if no alarm is selected).
7. List of alarms
  - Select (checkbox)
  - Timestamp
  - Source
  - Alarm
  - Comment
8. Update-related information:
  - Time of last update unknown  
No manual or automatic update has been performed yet.
  - Update in progress  
Operator has tapped the **Get** button or the automatic update is currently being performed.
  - Last update completed (<timestamp>)  
After an update has been completed successfully.
  - Last update failed (<timestamp>)  
After an update has failed. Phase displays the **Connection Error (SR0500.3.6.1)** error message ([GID-2668708](#)).
9. **Confirm** button.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

#### 4.1.1.3 GID-2670214 COMPLETED MODE (SR0500.1.3)

1. Instruction table panel and/or instruction link panel  
(only if an instruction table and/or instruction link is defined for the phase)
2. <Instruction text>  
(taken from **Instruction (SR0500.8.1)** process parameter ([GID-2670224](#)))
3. Start: <timestamp>  
End: <timestamp>

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4. DCS name: <logical name>  
Batch ID: <identifier> Unit ID: <identifier>  
Modules: <list of identifiers>  
(taken from **DCS (SR0500.8.2)** process parameter [\(GID-2670225\)](#) and **Filter criteria (SR0500.8.3)** process parameter [\(GID-2670226\)](#))
5. Number of retrieved alarms: <value>
6. **Confirm** button (completed).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

#### 4.1.2 *Representation in Navigator (SR0500.4+)*

The Navigator provides the following details:

##### 4.1.2.1 PHASE COLUMN (FRAMEWORK CAPABILITY)

- <Phase name>
  - Example:  
Collect mixer alarms

##### 4.1.2.2 GID-2670216 INFORMATION COLUMN (SR0500.4.1)

- <Number of retrieved alarms>
  - Example: 27

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	Medium
MES-Compliance: 21 CFR Part 11 relevance	No

##### 4.1.2.3 ACTION COLUMN

- There are no phase-specific actions available.

#### 4.1.3 *Representation in Sub-report (SR0500.5+)*

The sub-report contains the following information:

##### 4.1.3.1 COMMON SUB-REPORT ELEMENTS (FRAMEWORK CAPABILITY)

- <Start time>
- <Completion time>

- <Unit procedure> / <operation> / <phase>
- <Work center> / <station> / <device> - <phase completion user>

#### 4.1.3.2 GID-2670219 SUB-REPORT ELEMENTS (SR0500.5.1)

- Instruction table panel and/or instruction link panel  
(only if an instruction table and/or instruction link is defined for the phase)
- DCS name: <logical name>  
Batch ID: <identifier>  
Unit ID: <identifier>  
Start: <timestampl>  
End: <timestampl>  
Modules: <list of identifiers>
- List of alarms
- Timestamp
- Source
- Alarm
- Comment
- Alarm converted

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

## 4.2 Business Logic (SR0500.2+)

The phase implements the following business logic.

### 4.2.1 GID-2668694 Retrieve alarms without automatic update (SR0500.2.1)

- Function: Manually retrieve alarms from the DCS
- Trigger: Phase becomes active
- Postcondition: Phase is completed

Step	#	Description
Phase activation	10	Phase displays its user interface according to the <b>Active mode</b> ( <b>SR0500.1.2</b> ) layout ( <a href="#">GID-2670213</a> ) with an empty list of alarms.
Operator taps <b>Get</b> button	20	Phase retrieves alarms from the DCS. <ul style="list-style-type: none"> <li>▪ If alarms cannot be retrieved, phase displays <b>Connection error</b> (<b>SR0500.3.6.1</b>) error message (<a href="#">GID-2668708</a>).</li> </ul>

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Step	#	Description
		<ul style="list-style-type: none"> <li>If no error has occurred, phase displays the retrieved alarms at the top of the list of alarms.</li> </ul>
Operator selects alarms for conversion	30	See Convert alarms into exception (SR0500.2.3) function ( <a href="#">GID-2668696</a> ).
Operator confirms phase	40	See Confirm phase (SR0500.2.4) function ( <a href="#">GID-2668697</a> ).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

#### 4.2.2 *GID-2668695 Retrieve alarms with automatic update (SR0500.2.2)*

- Function: Automatically retrieve alarms from the DCS
- Trigger: Phase becomes active
- Postcondition: Phase is completed

Step	#	Description
Phase activation	10	Phase displays its user interface according to the <b>Active mode (SR0500.1.2)</b> layout ( <a href="#">GID-2670213</a> ) with the list of retrieved alarms.
Phase retrieves alarms	20	<p>Within the defined interval (<b>Automatic update (SR0500.8.4)</b> process parameter (<a href="#">GID-2670228</a>)), phase retrieves alarms and updates phase representation.</p> <ul style="list-style-type: none"> <li>▪ If alarms cannot be retrieved, phase displays the <b>Connection error (SR0500.3.6.1)</b> error message (<a href="#">GID-2668708</a>) (only if the phase's Active mode is the current view). The error message is only displayed once and does not stack for further occurrences.</li> <li>▪ If there are new alarms, phase displays them at the top of the list of alarms and displays the <b>New alarms retrieved (SR0500.3.4.1)</b> information message (<a href="#">GID-2668707</a>) (only if the phase's Active mode is the current view). The information message is only displayed once and does not stack for further occurrences.</li> </ul> <p>A new alarm is detected by finding a difference between the current time and previously retrieved alarms. The timestamp, source, alarm, and comment of the alarms are compared.</p> <ul style="list-style-type: none"> <li>▪ Retrieval is terminated when the operator confirms the phase (see step 50).</li> </ul>

Step	#	Description
Operator taps <b>Get</b> button	30	<p>Phase retrieves alarms from the DCS.</p> <ul style="list-style-type: none"> <li>If alarms cannot be retrieved, phase displays <b>Connection error (SR0500.3.6.1)</b> error message (<a href="#">GID-2668708</a>).</li> <li>If no error has occurred, phase displays the retrieved alarms at the top of the list of alarms.</li> </ul>
Operator selects alarms for conversion	40	See <b>Convert alarms into exception (SR0500.2.3)</b> function ( <a href="#">GID-2668696</a> ).
Operator confirms phase	50	See <b>Confirm phase (SR0500.2.4)</b> function ( <a href="#">GID-2668697</a> ).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

#### 4.2.3 **GID-2668696 Convert alarms into exceptions (SR0500.2.3)**

Function: Retrieved alarms are converted into an exception

Trigger: Operator taps **Exception** button in **Active mode (SR0500.1.2)** layout ([GID-2670213](#)) to convert selected alarms into an exception

Postcondition: Selected alarms are converted into an exception and are no longer displayed in the list of alarms

Step	#	Description
Operator selects alarms for conversion	10	<b>Exception</b> button in <b>Active mode (SR0500.1.2)</b> layout ( <a href="#">GID-2670213</a> ) becomes active.
Operator taps <b>Exception</b> button in <b>Active mode (SR0500.1.2)</b> layout	20	<p>Phase creates <b>Alarm exception (SR0500.3.1.1)</b> user-triggered exception (<a href="#">GID-2670239</a>)</p> <p>If selected alarms have already been converted by an operator within another Production Execution Client in the context of an event-triggered operation, phase displays <b>Alarms already converted (SR0500.3.6.2)</b> error message (<a href="#">GID-2668709</a>).</p>

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

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#### 4.2.4 GID-2668697 Confirm phase (SR0500.2.4)

- Function: Completion of phase
- Trigger: Operator confirms phase
- Postcondition: Phase is completed

Step	#	Description
Phase performs completion checks	10	<ul style="list-style-type: none"> <li>▪ Phase polls DCS for new alarms. If there are new alarms, phase displays them at the top of the list of alarms and displays <b>New alarms retrieved (SR0500.3.4.1)</b> information message. A new alarm is detected by finding a difference between the current time and previously retrieved alarms. The timestamp, source, alarm, and comment of the alarms are compared.</li> <li>▪ If alarms cannot be retrieved, phase creates <b>Retrieval exception (SR0500.3.2.1)</b> system-triggered exception (<a href="#">GID-2670234</a>). This exception has to be recorded only once.</li> <li>▪ Phase checks for not yet converted alarms only if the check has been enabled with the <b>Unconverted alarms (SR0500.8.6)</b> process parameter (<a href="#">GID-2670230</a>) If there are unconverted alarms, phase creates <b>Unconverted alarms (SR0500.3.2.2)</b> system-triggered exception link. This exception has to be recorded each time unconverted alarms are detected.</li> </ul>
Phase completion	20	Phase is completed.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

#### 4.2.5 GID-2668698 Run several phases within an order (SR0500.2.6)

- Function: Several **Get DCS alarms** phases within the same order for the same target DCS
- Trigger: A subsequent phase instance becomes active
- Postcondition: N/A

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Step	#	Description
Phase activation	10	Alarms that have already been converted by previous instances of the <b>Get DCS alarms</b> phase are not displayed again. Phase displays its user interface according to the <b>Active mode (SR0500.1.2)</b> layout ( <a href="#">GID-2670213</a> ) with the list of still unconverted alarms according to the shared filter criteria defined with the <b>Filter criteria (SR0500.8.3)</b> process parameter ( <a href="#">GID-2670226</a> ).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

## 4.3 Process Parameters (SR0500.8+)

The following process parameters define the behavior of the phase.

### 4.3.1 *Instruction Table-specific Parameters*

#### 4.3.1.1 INSTRUCTION TABLE DEFINITION (FRAMEWORK CAPABILITY)

Attribute	Type	Comment
Table layout	Choice list	Defines the layout of the instruction table holding the instruction texts. Available settings: <b>1 column</b> , <b>2 columns</b> , <b>3 columns</b> , <b>4 columns</b> , <b>5 columns</b> . Default setting: <b>1 column</b> .
First column narrow	Boolean	Defines if the first column of the table shall be narrow.
Show all borders	Boolean	Defines if the borders of the table shall be visible.

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#### 4.3.1.2 INSTRUCTION TABLE TEXT (FRAMEWORK CAPABILITY)

Attribute	Type	Comment
Column 1	HTML text	Instruction text to be displayed in a column.
Column 2	HTML text	<b>Restriction:</b> Maximum length is 2000 characters (including HTML tags).
Column 3	HTML text	
Column 4	HTML text	
Column 5	HTML text	

#### 4.3.2 Instruction link-specific parameters

##### 4.3.2.1 INSTRUCTION TEXT WITH LINKS (FRAMEWORK CAPABILITY)

Attribute	Type	Comment
Instruction text	HTML text	<p>Instruction text to be displayed. For any text enclosed in curly brackets you can define a hyperlink with the <b>Instruction link definition</b> process parameter link. Example: Refer to {SOP1270} for guidance.</p> <p>Maximum length is 2000 characters (including HTML tags).</p>

##### 4.3.2.2 INSTRUCTION LINK DEFINITION (FRAMEWORK CAPABILITY)

Attribute	Type	Comment
Link text	Text	<p>Text to be used as link. For any text enclosed in curly brackets within the instruction text you can define a link with the <b>Link URL</b> attribute. Including the brackets in the link text is optional.</p> <p>Maximum length is 80 characters.</p>

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Attribute	Type	Comment
Link URL	Text	URL of the file to be displayed. The link opens the external application assigned to the file type by the operating system. Maximum length is 256 characters.

#### 4.3.3 Basic Parameters

##### 4.3.3.1 GID-2670224 INSTRUCTION (SR0500.8.1)

Attribute	Type	Comment
Text	HTML text	Instruction text to be displayed. <b>Restriction:</b> Maximum length is 4000 characters (including HTML tags).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

##### 4.3.3.2 GID-2670225 DCS (SR0500.8.2)

Attribute	Type	Comment
Name	String	Logical name of the DCS to be used. The available entries correspond to the entries in the <b>DCSNames</b> list. Default setting: First entry in the list. Maximum length is 255 characters.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

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#### 4.3.3.3 GID-2670226 FILTER CRITERIA (SR0500.8.3)

Attribute	Type	Comment
Batch ID	String	Optional parameter to define the identifier of the batch running on the DCS. Maximum length is 250 characters. If not defined, phase displays "N/A".
Unit ID	String	Optional parameter to define the identifier of a unit of the DCS. Maximum length is 250 characters. If not defined, phase displays "N/A".
Query start	Timestamp	Optional parameter to set the start timestamp from which on the alarms are queried. If not defined, phase displays "N/A".
Query end	Timestamp	Optional parameter to set the end timestamp up to which the alarms are queried. If not defined, phase displays "N/A".
Module IDs	Text (structured)	Optional parameter to define the list of equipment module IDs and control module IDs. Maximum length is 2000 characters. If not defined, phase displays "N/A".

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

#### 4.3.3.4 LIST EDITOR (FRAMEWORK CAPABILITY)

The system provides a List editor for entering list items.

#### 4.3.3.5 GID-2670228 AUTOMATIC UPDATE (SR0500.8.4)

Attribute	Type	Comment
Enabled	Boolean	Controls if the query is repeated automatically. If so, ensure that the <b>Update interval</b> attribute is defined.
Update interval	Duration	Defines the interval between re-querying. The minimum interval is set to 1 minute if the interval is not defined at all or configured to be less than that.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

#### 4.3.4 Configuration of System-triggered Exceptions

##### 4.3.4.1 GID-2670229 RETRIEVAL EXCEPTION (SR0500.8.5)

Attribute	Type	Comment
Risk assessment	Choice list	Defines the risk level of the exception and thus controls the related signature privilege. Available settings: <b>None</b> , <b>Low</b> , <b>Low (mandatory comment)</b> , <b>Medium</b> , <b>Medium (mandatory comment)</b> , <b>High</b> , <b>High (mandatory comment)</b> . Default setting: <b>High</b> .
Exception text	Text	Defines the exception description used during exception handling and within the batch record. Maximum length is 250 characters.

See also **Retrieval exception (SR0500.3.2.1)** system-triggered exception [\(GID-2670234\)](#)

Attribute	Value
MES-Business: GxP relevance	No
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

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#### 4.3.4.2 GID-2670230 UNCONVERTED ALARMS (SR0500.8.6)

Attribute	Type	Comment
Enabled	Flag	Controls if a check is performed. Default setting: Yes
Risk assessment	Choice list	Defines the risk level of the exception and thus controls the related signature privilege. Available settings: <b>None</b> , <b>Low</b> , <b>Low (mandatory comment)</b> , <b>Medium</b> , <b>Medium (mandatory comment)</b> , <b>High</b> , <b>High (mandatory comment)</b> . Default setting: <b>High</b> .
Exception text	Text	Defines the exception description used during exception handling and within the batch record. Maximum length is 250 characters.

See also Unconverted alarms (SR0500.3.2.2) system-triggered exception ([GID-2670236](#)).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

#### 4.3.5 Configuration of User-triggered Exceptions

##### 4.3.5.1 GID-2670231 RECORD ALARM EXCEPTION (SR0500.8.7)

Attribute	Type	Comment
Risk assessment	Choice list	Defines the risk level of the exception and thus controls the related signature privilege. Available settings: <b>None</b> , <b>Low</b> , <b>Low (mandatory comment)</b> , <b>Medium</b> , <b>Medium (mandatory comment)</b> , <b>High</b> , <b>High (mandatory comment)</b> . Default setting: <b>High</b> .

- Get DCS Alarms Phase (SR0500+)
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Attribute	Type	Comment
Exception text	Text	Defines the exception description used during exception handling and within the batch record. Maximum length is 250 characters.

See also [Alarm exception \(SR0500.3.1.1\)](#) user-triggered exception ([GID-2670239](#)).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

#### 4.3.5.2 GID-2670232 ONE ALARM PER EXCEPTION (SR0500.8.8)

Attribute	Type	Comment
Enabled	Boolean	Controls how alarms are converted into exceptions. If enabled, for each alarm to be converted, a new exception is created and the alarm data is added to the exception text. If not enabled, one exception is created and for each alarm to be converted, a new comment with the alarm data is added to the exception. Default setting: No.

See also [Alarm exception \(SR0500.3.1.1\)](#) user-triggered exception ([GID-2670239](#))

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

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#### 4.3.5.3 GID-2670233 ONE EXCEPTION PER UNCONVERTED ALARM (SR0500.8.9)

Attribute	Type	Comment
Enabled	Boolean	<p>Only relevant if the <b>Unconverted Alarm (SR0500.8.6)</b> system-triggered exception (<a href="#">GID-2670230</a>) (<a href="#">GID-2670230</a>) is enabled.</p> <p>Controls how exceptions for unconverted alarms are created. If enabled, for each unconverted alarm, a new exception is created, and the alarm data is added to the exception text. If not enabled, one exception is created and for each unconverted alarm, a new comment with the alarm data is added to the exception.</p> <p>Default setting: <b>No</b>.</p>

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

### 4.4 Exceptions (SR0500.3+)

The phase supports user-defined, user-triggered ([GID-2668705](#)), system-triggered ([GID-2668704](#)), and post-completion exceptions ([GID-2668706](#)) and their configuration by means of process parameters (come back link).

User-defined exceptions cannot be configured by process parameters since they are provided by the framework and independent of phases.

#### 4.4.1 System-triggered Exceptions (SR0500.3.2+)

A system-triggered exception is represented in a message dialog along with an **Exception** button, in the Exception Window as the read-only description of the exception, and in the batch report.

The following system-triggered exceptions are available.

##### 4.4.1.1 GID-2670234 RETRIEVAL EXCEPTION (SR0500.3.2.1)

Representation of the exception:

- <Exception text>  
(taken from **Retrieval exception (SR0500.8.5)** process parameter ([GID-2670229](#)))  
No alarms could be retrieved from the DCS.

- Example:
  - Issues with alarm retrieval
  - No alarms could be retrieved from the DCS.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

#### 4.4.1.2 GID-2670235 RETRIEVAL EXCEPTION - LOGIC (SR0500.3.2.1.1)

- Trigger: Alarms could not be retrieved from the DCS
- Postcondition: Exception is recorded

Step	#	Description
Operator accepts exceptional situation	10	Phase shows exception description to be signed.
Operator signs exception	20	Phase records the exception.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

#### 4.4.1.3 GID-2670236 UNCONVERTED ALARMS (SR0500.3.2.2)

The unconverted alarms exception is triggered by the system automatically if the phase is confirmed, the **Unconverted alarms (SR0500.8.6)** system-triggered exception is enabled, and not all retrieved alarms have already been converted.

Representation of the exception when the **One exception per unconverted alarm (SR0500.8.9)** process parameter ([GID-2670233](#)) is not enabled:

- <Exception text>  
(taken from **Unconverted alarms (SR0500.8.6)** process parameter ([GID-2670230](#)))  
Number of unconverted alarms: <value>

First comment of exception:

Timestamp: <timestamp of first alarm> / Source: <source of first alarm>

Alarm: <first alarm>

Comment: <comment of first alarm, if available>

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Last comment of exception:

Timestamp: <timestamp of last alarm> / Source: <source of last alarm>

Alarm: <last alarm>

Comment: <comment of last alarm, if available>

- Example:  
Unconverted alarms  
Number of unconverted alarms: 2
- [Comment 1]Timestamp: 02/21/2016 14:35:29 PM CEST / Source: PV51525/ST-PV51525-001  
Alarm: Attr: LO\_ALM Alarm Work: LOW State: ACT/UNACK Level:  
15-CRITICAL Descript: Low Alarm Value 105 338 Limit 110  
Comment: Adjusted pressure by 4 psi oraita, 12:40:12 13-Nov-2015  
[Comment 2]Timestamp: 02/21/2016 14:36:12 PM CEST / Source:  
PV51525/ST-PV51525-001  
Alarm: Attr: LO\_ALM Alarm Work: LOW State: INACT/UNACK Level:  
15-CRITICAL Descript: Low Alarm Value 119 234 Limit 110

Representation of the exception when the **One exception per unconverted alarm (SR0500.8.6)** process parameter ([\(GID-2670230\)](#)) is enabled:

- First Alarm Exception text:  
<Exception text>  
(taken from **Unconverted alarms (SR0500.8.6)** process parameter ([\(GID-2670230\)](#)))  
Number of unconverted alarms: <value>  
Timestamp: <timestamp of first alarm> / Source: <source of first alarm>  
Alarm: <first alarm>  
Comment: <comment of first alarm, if available>

Second Alarm Exception text:

<Exception text>

(taken from **Unconverted alarms (SR0500.8.6)** process parameter ([\(GID-2670230\)](#)))

Unconverted alarm

Timestamp: <timestamp of second alarm> / Source: <source of second alarm>

Alarm: <second alarm>

Comment: <comment of second alarm, if available>

:

Last Alarm Exception text:

<Exception text>

(taken from **Unconverted alarms (SR0500.8.6)** process parameter ([\(GID-2670230\)](#)))

Unconverted alarm

Timestamp: <timestamp of last alarm> / Source: <source of last alarm>

Alarm: <last alarm>

Comment: <comment of last alarm, if available>

- Example:  
[Exception]Some alarms were not converted.  
Number of unconverted alarms: 2  
Timestamp: 02/21/2016 14:35:29 PM CEST / Source: PV51525/ST-PV51525-001  
Alarm: Attr: LO\_ALM Alarm Work: LOW State: ACT/UNACK Level:  
15-CRITICAL Descript: Low Alarm Value 105 338 Limit 110  
Comment: Adjusted pressure by 4 psi oraita, 12:40:12 13-Nov-2015
- [Exception]Some alarms were not converted.  
Unconverted alarm  
Timestamp: 02/21/2016 14:36:12 PM CEST / Source:  
PV51525/ST-PV51525-001  
Alarm: Attr: LO\_ALM Alarm Work: LOW State: INACT/UNACK Level:  
15-CRITICAL Descript: Low Alarm Value 119 234 Limit 110

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

#### 4.4.1.4 GID-2670237 UNCONVERTED ALARMS - LOGIC (SR0500.3.2.2.1)

- Trigger: At least one alarm has not been converted to an exception at phase completion
- Postcondition: Exception is recorded

Step	#	Description
Operator accepts exceptional situation	10	Phase shows exception description to be signed.
Operator signs exception	20	Phase records the exception and creates one comment per unconverted alarm or one exception per unconverted alarm, based on the <b>One exception per unconverted alarm (SR0500.8.9)</b> process parameter ( <a href="#">GID-2670233</a> ). The unconverted alarms are no longer displayed in the list of alarms of the <b>Active mode (SR0500.1.2)</b> layout ( <a href="#">GID-2670213</a> )

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

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#### 4.4.1.5 GID-2670238 MULTIPLE SYSTEM-TRIGGERED EXCEPTIONS (SR0500.3.2.3)

In case multiple system-triggered exceptions occur, only one combined exception (system-triggered exception) is recorded including information about all exceptions. The highest risk assessment of all related exceptions and its related signature privilege apply.

When the exception has been recorded, the phase is completed automatically.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

#### 4.4.2 User-triggered Exceptions (SR0500.3.1+)

A user-triggered exception is represented in the list of available user-triggered exceptions in the Exception Window, as the description of the exception, and in the batch report.

The **Get DCS alarms** phase provides an **Exception** button in the Execution Window to record user-triggered exceptions.

The following user-triggered exceptions are available.

##### 4.4.2.1 GID-2670239 ALARM EXCEPTION (SR0500.3.1.1)

The **Alarm exception** allows an operator to convert selected alarms from the DCS into phase-specific exceptions based on the configuration maintained with the **One alarm per exception (SR0500.8.8)** process parameter ([GID-2670232](#)).

Representation of the exception when the **One alarm per exception (SR0500.8.8)** process parameter ([GID-2670232](#)) is not enabled:

- Exception text:  
<Exception text>  
(taken from Record alarm exception (SR0500.8.8) process parameter ([GID-2670232](#)))  
<value> alarms have been converted.

First comment of exception:

Timestamp: <timestamp of first alarm> / Source: <source of first alarm>

Alarm: <first alarm>

Comment: <comment of first alarm, if available>

:

Last comment of exception:

Timestamp: <timestamp of last alarm> / Source: <source of last alarm>

Alarm: <last alarm>

Comment: <comment of last alarm, if available>

- Example:  
List of alarms converted into exceptions  
2 alarms have been converted.  
[Comment]Timestamp: 02/21/2016 14:35:29 PM CEST / Source: PV51525/ST-PV51525-

001

Alarm: Attr: LO\_ALM Alarm Work: LOW State: ACT/UNACK Level: 15-CRITICAL

Descript: Low Alarm Value 105 338 Limit 110

Comment: Adjusted pressure by 4 psi oraita, 12:40:12 13-Nov-2015

[Comment]Timestamp: 02/21/2016 14:36:12 PM CEST / Source: PV51525/ST-PV51525-001

Alarm: Attr: LO\_ALM Alarm Work: LOW State: INACT/UNACK Level: 15-CRITICAL

Descript: Low Alarm Value 119 234 Limit 110

Representation of the exception when the **One alarm per exception (SR0500.8.8)** process parameter ([GID-2670232](#)) ([GID-2670232](#)) is enabled:

- First Alarm Exception text:

<Exception text>

(taken from **Record alarm exception (SR0500.8.7)** process parameter ([GID-2670231](#)))

First exception:

<value> alarms have been converted.

Timestamp: <timestamp of first alarm> / Source: <source of first alarm>

Alarm: <first alarm>

Comment: <comment of first alarm, if available>

Second Alarm Exception text:

<Exception text>

(taken from **Record alarm exception (SR0500.8.7)** process parameter ([GID-2670231](#)))

Alarm has been converted (See exception: <First Exception Identifier>)

Timestamp: <timestamp of second alarm> / Source: <source of second alarm>

Alarm: <second alarm>

Comment: <comment of second alarm, if available>

:

Last Alarm Exception text:

<Exception text>

(taken from **Record alarm exception (SR0500.8.7)** process parameter ([GID-2670231](#)))

Alarm has been converted (See exception: <First Exception Identifier>)

Timestamp: <timestamp of lastalarm> / Source: <source of last alarm>

Alarm: <last alarm>

Comment: <comment of last alarm, if available>

- Example

[Exception] List of alarms converted into exceptions

2 alarms have been converted.

Timestamp: 02/21/2016 14:35:29 PM CEST / Source: PV51525/ST-PV51525-001

Alarm: Attr: LO\_ALM Alarm Work: LOW State: ACT/UNACK Level: 15-CRITICAL

Descript:

Low Alarm Value 105 338 Limit 110

Comment: Adjusted pressure by 4 psi oraita, 12:40:12 13-Nov-2015

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[Exception] List of alarms converted into exceptions

Alarm has been converted (see exception: 002) Timestamp: 02/21/2016 14:36:12 PM CEST /

Source: PV51525/ST-PV51525-001

Alarm: Attr: LO\_ALM Alarm Work: LOW State: INACT/UNACK Level: 15-CRITICAL

Descript:

Low Alarm Value 119 234 Limit 110

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

#### 4.4.2.2 GID-2670240 ALARM EXCEPTION - LOGIC (SR0500.3.1.1.1)

- Trigger: Operator taps **Exception** button in **Active mode (SR0500.1.2)** layout ([GID-2670213](#)) to convert selected alarms into exceptions
- Postcondition: Selected alarms are converted into exceptions and are no longer displayed in the list of alarms

Step	#	Description
Operator taps <b>Exception</b> button	10	Phase shows exception description to be signed.
Operator signs exception	20	Phase records the exception and created a comment per converted alarm or one exception per converted alarm, based on the <b>One alarm per exception (SR0500.8.8)</b> process parameter ( <a href="#">GID-2670232</a> ).  The converted alarms are no longer displayed in the list of alarms of the <b>Active mode (SR01500.01.2)</b> layout ( <a href="#">GID-2670213</a> ).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

#### 4.4.3 Post-completion Exceptions

There are no post-completion exceptions available.

### 4.5 Information Messages (SR0500.3.4+)

Information messages are represented in an information dialog containing a message type-specific icon, the information message, and an **OK** button.

The following information messages are available to inform the operator about how to proceed.

#### 4.5.1 *GID-2668707 New alarms retrieved (SR0500.3.4.1)*

UI text	Comment
There are <value> new alarms.	Message pack: PhaseDCSGetDCSAlarms<version> Message ID: NewAlarms_Msg
There is 1 new alarm.	Message pack: PhaseDCSGetDCSAlarms<version> Message ID: OneNewAlarm_Msg

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	Low
MES-Compliance: 21 CFR Part 11 relevance	No

#### 4.6 Questions

There are no questions available.

#### 4.7 Decisions

There are no decisions available.

#### 4.8 Error Messages (SR0500.3.6+)

Error messages are represented in an error message dialog containing a message type-specific icon, the error message, and an **OK** button.

The following error messages are available to inform the operator about error conditions.

#### 4.8.1 *GID-2668708 Connection error (SR0500.3.6.1)*

UI text	Comment
Cannot retrieve alarms from the DCS.	Message pack: PhaseDCSGetDCSAlarms<version> Message ID: GetAlarms_Error

The **Details** button provides access to more specific technical information.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

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#### **4.8.2 GID-2668709 Alarms already converted (SR0500.3.6.2)**

UI text	Comment
One or more of the selected alarms were already converted in another run of the phase.	Message pack: PhaseDCSGetDCSAlarms<version> Message ID: AlarmsAlreadyConverted_Error

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

### **4.9 Output Variables (SR0500.9+)**

The following output variables are available to reference the phase's output.

#### **4.9.1 Instance count (Framework capability)**

- Data type: Long
- Usage: The output variable provides the count of the number of instances the phase has been processed, for example in a loop. The count is also increased when the phase is skipped from an operator's perspective, since the phase is still executed, but as a hidden phase.  
The count variable of a phase that has not been executed provides 0 as output value.

#### **4.9.2 Start time (Framework capability)**

- Data type: Timestamp
- Usage: The output variable provides the start time of the phase.

#### **4.9.3 Completion time (Framework capability)**

- Data type: Timestamp
- Usage: The output variable provides the completion time of the phase.

#### **4.9.4 Identifier (Framework capability)**

- Data type: String
- Usage: The output variable provides the identifier of the phase.

#### **4.9.5 GID-2668714 Number of retrieved alarms (SR0500.9.1)**

- Data type: Long
- Usage: The output variable provides the number of alarms that were retrieved by the phase.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

#### 4.9.6 *GID-2668715 Number of converted alarms (SR0500.9.2)*

- Data type: Long
- Usage: The output variable provides the number of alarms that were converted into exceptions.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

### 4.10 Configuration Keys (SR0500.11+)

The following configuration keys are available to configure the phase's behavior.

#### 4.10.1 *GID-2668716 Message broker URL (SR0500.11.1)*

- Phase/DCS/DCSMessagesBrokerURL
- **Type:** String
- **Value:** tcp://<hostname>:<port>
- **Description:** Specifies the URL of the messaging server used for DCS communication. Replace <hostname> with the name of the host to be used and <port> with the port number of the host to be used.  
If no value is set, the URL defined in the PharmaSuite **MessageBrokerURL** configuration key is used.
- **Evaluated:** When a DCS phase communicates with a DCS.
- **Range:** N/A

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

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#### **4.10.2 GID-2668717 Messaging timeout (SR0500.11.2)**

- Phase/DCS/DCSMessagingTimeout
- **Type:** Long
- **Value:** 2
- **Description:** The messaging timeout for DCS communication in seconds and the time how long a produced DCS message shall be retained by the messaging system after it has been dispatched.  
If no value is set, the timeout defined in the PharmaSuite **MessagingTimeout** configuration key is used (converted into seconds).
- **Evaluated:** When a DCS phase communicates with a DCS.
- **Range:** N/A

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

#### **4.10.3 GID-2668718 Too long alarm exception risk (SR0500.11.3)**

- Phase/GetDCSAlarms/TooLongAlarmExceptionRisk
- **Type:** Long
- **Value:** 30  
(Value of the **High risk** level)
- **Description:** The exception-specific risk level of an automatic exception added to a **Get DCS alarms** phase when a too long alarm is received.
- **Evaluated:** When the **Get DCS alarms** phase is started in the Production Execution Client.
- **Range:** The meaning of the elements of the **RiskClass** choice list.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

## 5 DCS Alarm-based Trigger Phase (SR0510+)

The **DCS alarm-based trigger** phase allows to automatically create runs of an event-triggered operation (ETO) based on DCS alarms whenever new DCS alarms are retrieved in the defined check cycle.

Example use cases are:

- Several operators are responsible for a production area in which several orders are executed. The operators have to be notified when new alarms have been retrieved from the DCS. Subsequently, an operator can document the alarms as PharmaSuite exceptions.

The configuration of the alarm query, number of retrieved alarms, fired triggers and their time information is stored in the batch record, thereby becoming available for documentation purposes in the sub-report and batch report ([GID-2668721](#)).

Anomalies that occur during processing are covered by the phase exception handling ([GID-2667689](#)) (e.g. timeout of the phase).

### 5.1 Layout

The phase provides a layout for its representation in the sub-report ([GID-2668721](#)).

#### 5.1.1 Representation during Execution

As a server-run phase, the phase has no graphical representation (UI).

#### 5.1.2 Representation in Navigator

As a server-run phase, the phase is not visible in the Navigator.

#### 5.1.3 Representation in Sub-report (SR0510.5+)

The sub-report contains the following information:

##### 5.1.3.1 COMMON SUB-REPORT ELEMENTS (FRAMEWORK CAPABILITY)

- <Start time>
- <Completion time>
- <Unit procedure> / <operation> / <phase>
- <Work center> / <station> / <device> - <phase completion user>

For phases running on a server, the phase completion-user corresponds to the system.

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### 5.1.3.2 GID-2670242 SUB-REPORT ELEMENTS (SR0510.5.1)

- DCS name: <logical name>  
Batch ID: <identifier>  
Unit ID: <identifier>  
Start: <timestamp>  
End: <timestamp>  
Modules: <list of identifiers>
- Number of retrieved alarms: <value>
- Number of executed triggers: <value>
- List of pause events: Paused from <timestamp> until <timestamp>

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

## 5.2 Business Logic (SR0510.2+)

The phase implements the following business logic.

### 5.2.1 GID-2668722 Phase activation (SR0510.2.1)

- Function: Start the trigger processing
- Trigger: Phase becomes active
- Postcondition: Trigger processing is started

Step	#	Description
Phase activation	10	<p>Phase checks</p> <ul style="list-style-type: none"> <li>▪ if the unit procedure is currently paused (check passes if the unit procedure is not paused),</li> <li>▪ if at least one of the relevant ETO templates is already active (check passes if at least one ETO template is active), and</li> <li>▪ if the timeout period has not elapsed yet (defined with the <b>Timeout period (SR0510.8.4)</b> process parameter (<a href="#">GID-2670247</a>)) (check passes if an ETO template has become active before the timeout period has elapsed).</li> </ul> <p>If all checks have passed, continue with step 10.4.</p>
	10.1	If the unit procedure is paused, the phase waits without any action (no trigger processing, no timeout clock is running) until the unit procedure is continued.

Step	#	Description
	10.2	If the unit procedure is running, no relevant ETO template is active, and the timeout period has not elapsed, trigger processing is still waiting and timeout clock is running.
	10.3	If the timeout period has elapsed without any ETO becoming active, the phase is completed automatically according to the <b>Phase completion (SR0510.2.5)</b> function ( <a href="#">GID-2668726</a> ).
	10.4	If a relevant ETO template becomes active, trigger processing starts according to the <b>Fire triggers (SR0510.2.2)</b> function ( <a href="#">GID-2668723</a> ). At this point, the timeout period no longer applies.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

### 5.2.2 *GID-2668723 Fire triggers (SR0510.2.2)*

- Function: Fire the triggers
- Trigger: Trigger processing has started
- Postcondition: Triggers are fired

Step	#	Description
Start trigger processing	10	Phase retrieves alarms from the DCS and starts to repeatedly retrieve alarms from the DCS according to the interval defined with the <b>Duration</b> attribute of the <b>Retrieving cycle (SR0510.8.3)</b> process parameter ( <a href="#">GID-2670246</a> ).
	20	Phase repeatedly fires a trigger, each time new alarms have been retrieved from the DCS.  A new alarm is detected by finding a difference between the current time and previously retrieved alarms. The TimeStamp, Value, EquipmentID and MessageText of the AlarmEvent are compared.
DCS Adapter is not available	20.1	With respect to the alarms that could not be retrieved, phase creates a <b>Retrieval exception (SR0510.3.2.2)</b> system-triggered exception ( <a href="#">GID-2670253</a> ).

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Step	#	Description
		<p>As soon as the DCS Adapter becomes available again, phase retrieves the current alarms and continues to fire triggers according to the <b>Fire trigger (SR0510.2.2)</b> function.</p> <p>The system adds a comment to the already recorded exception according to the <b>Retrieval exception - Resume (SR0510.3.2.2.2)</b> function (<a href="#">GID-2670255</a>) of the <b>Retrieval exception (SR0510.3.2.2)</b> system-triggered exception (<a href="#">GID-2670253</a>).</p>

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

### 5.2.3 *GID-2668724 Pause trigger processing (SR0510.2.3)*

- Function: Pause/continue the trigger processing
- Precondition: Trigger processing is active
- Trigger: Unit procedure is paused/continued by the operator (for details, see **Pausing a Unit Procedure (SR1089.8.3)** in "Functional Requirement Specification Execution Framework" [A1])
- Postcondition: Trigger processing is paused/continued

Step	#	Description
Operator pauses unit procedure	10	When the unit procedure of the phase is paused, trigger processing stops. No further triggers are fired automatically.
Operator continues paused unit procedure	20.1	When the paused unit procedure of the phase is continued, trigger processing continues according to the <b>Fire triggers (SR0510.2.2)</b> function ( <a href="#">GID-2668723</a> ).
	20.2	In case no relevant ETO template was active during the pause period and the timeout period has not elapsed yet: trigger processing is still waiting and the timeout clock is running, however, the timeout clock is reset upon resume of the pause.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

#### **5.2.4 GID-2668725 Resume trigger processing (SR0510.2.4)**

- Function: Resume the trigger processing  
(for the continuation of a paused unit procedure, see **Pause trigger processing (SR0510.2.3)** function ([GID-2668724](#)))
- Precondition: Trigger processing is active
- Trigger: Phase is restarted, e.g. along with the restart of the operation that runs on the OES (for details, see **Resuming Server-run Operations (SR1200.1.3)** in "Functional Requirement Specification Execution Framework" [A1])
- Postcondition: Triggers are fired

Step	#	Description
Phase is restarted or DCS Adapter becomes available again	10	As soon as the phase is restarted or the DCS Adapter becomes available again, it retrieves the current alarms and continues to fire triggers according to the <b>Fire triggers (SR0510.2.2)</b> function ( <a href="#">GID-2668723</a> ).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

#### **5.2.5 GID-2668726 Phase completion (SR0510.2.5)**

- Function: Completion of phase
- Trigger: Timeout period has elapsed or no ETO template is active anymore
- Postcondition: Phase is completed

Step	#	Description
Timeout period has elapsed	10	If the timeout period has elapsed, the phase is completed automatically without having fired any triggers and creates a <b>Timeout (SR0510.3.2.1)</b> system-triggered exception ( <a href="#">GID-2670251</a> ).
None of the previously running related ETO templates is active any more	20	Phase stops trigger processing and is completed automatically. If there are alarms for which no triggers have been fired, phase creates a <b>Post-ETO alarms (SR0510.3.2.3)</b> system-triggered exception ( <a href="#">GID-2670256</a> ).

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Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

## 5.3 Process Parameters (SR0510.8+)

The following process parameters define the behavior of the phase.

### 5.3.1 Basic Parameters

#### 5.3.1.1 GID-2670243 DCS (SR0510.8.1)

Attribute	Type	Comment
Name	String	Logical name of the DCS to be used. The available entries correspond to the entries in the <b>DCSNames</b> list. Default setting: First entry in the list. Maximum length is 255 characters.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

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### 5.3.1.2 GID-2670244 FILTER CRITERIA (SR0510.8.2)

Attribute	Type	Comment
Batch ID	String	Optional parameter to define the identifier of the batch running on the DCS. Maximum length is 250 characters. If not defined, phase displays "N/A" in the sub-report.
Unit ID	String	Optional parameter to define the identifier of a unit of the DCS. Maximum length is 250 characters. If not defined, phase displays "N/A" in the sub-report.
Query start	Timestamp	Optional parameter to set the start timestamp from which on the alarms are queried. If not defined, phase displays "N/A" in the sub-report.
Query end	Timestamp	Optional parameter to set the end timestamp up to which the alarms are queried. If not defined, phase displays "N/A" in the sub-report.
Module IDs	Text (structured)	Optional parameter to define the list of equipment module IDs and control module IDs. Maximum length is 2000 characters. If not defined, phase displays "N/A" in the sub-report.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

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### 5.3.1.3 LIST EDITOR (FRAMEWORK CAPABILITY)

The system provides a List editor for entering list items.

### 5.3.1.4 GID-2670246 RETRIEVING CYCLE (SR0510.8.3)

Attribute	Type	Comment
Duration	Duration	Defines the interval between two consecutive reading actions. The minimum interval is one minute. If a value of less than one minute is set or the interval is not defined at all, the system interprets this as one minute.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

### 5.3.1.5 GID-2670247 TIMEOUT PERIOD (SR0510.8.4)

Attribute	Type	Comment
Duration	Duration	Defines the duration that the phase waits for its event-triggered operation to become active, before the phase is automatically completed. Null is interpreted as 30 minutes (default timeout) during execution.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

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### 5.3.2 Configuration of System-triggered Exceptions

#### 5.3.2.1 GID-2670248 TIMEOUT EXCEPTION (SR0510.8.5)

Attribute	Type	Comment
Risk assessment	Choice list	Defines the risk level of the exception. Since there is no operator interaction for the exception, it is not linked to a signature privilege. Available settings: <b>None</b> , <b>Low</b> , <b>Low (mandatory comment)</b> , <b>Medium</b> , <b>Medium (mandatory comment)</b> , <b>High</b> , <b>High (mandatory comment)</b> . Default setting: <b>High</b> .
Exception text	Text	Defines the exception description used during exception handling and within the batch record. Maximum length is 250 characters.

See also Timeout (SR0510.3.2.1) system-triggered exception ([GID-2670251](#)).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

#### 5.3.2.2 GID-2670249 RETRIEVAL EXCEPTION (SR0510.8.6)

Attribute	Type	Comment
Risk assessment	Choice list	Defines the risk level of the exception. Since there is no operator interaction for the exception, it is not linked to a signature privilege. Available settings: <b>None</b> , <b>Low</b> , <b>Low (mandatory comment)</b> , <b>Medium</b> , <b>Medium (mandatory comment)</b> , <b>High</b> , <b>High (mandatory comment)</b> . Default setting: <b>High</b> .
Exception text	Text	Defines the exception description used during exception handling and within the batch record. Maximum length is 250 characters.

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See also **Retrieval exception (SR0510.3.2.2)** system-triggered exception [\(GID-2670253\)](#).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

### 5.3.2.3 GID-2670250 POST-ETO ALARMS EXCEPTION (SR0510.8.7)

Attribute	Type	Comment
Risk assessment	Choice list	Defines the risk level of the exception. Since there is no operator interaction for the exception, it is not linked to a signature privilege. Available settings: <b>None</b> , <b>Low</b> , <b>Low (mandatory comment)</b> , <b>Medium</b> , <b>Medium (mandatory comment)</b> , <b>High</b> , <b>High (mandatory comment)</b> . Default setting: <b>High</b> .
Exception text	Text	Defines the exception description used during exception handling and within the batch record. Maximum length is 250 characters.

See also **Post-ETO alarms exception (SR0510.3.2.3)** system-triggered exception [\(GID-2670256\)](#).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

## 5.4 Exceptions (SR0510.3+)

The phase supports system-triggered exceptions [\(GID-2668729\)](#) and their configuration by means of process parameters [\(GID-2667688\)](#).

### 5.4.1 System-triggered Exceptions (SR0510.3.2+)

A system-triggered exception of a server-run phase is automatically recorded in the batch report without any user interaction.

The following system-triggered exceptions are available.

#### 5.4.1.1 GID-2670251 TIMEOUT (SR0510.3.2.1)

In case the timeout period has elapsed, the system automatically records a system-triggered exception:  
Representation of the exception:

- <Exception text>  
(taken from **Timeout exception (SR0510.8.5)** process parameter ([GID-2670248](#)))  
Phase finished automatically due to timeout after <timeout period>.
- Example:  
Timeout occurred.  
Phase finished automatically due to timeout after 30 minutes.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

#### 5.4.1.2 GID-2670252 TIMEOUT - LOGIC (SR0510.3.2.1.1)

- Trigger: Phase is completed automatically due to timeout
- Postcondition: Exception is recorded

Step	#	Description
Timeout occurs	10	Phase automatically records exception without user interaction.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

#### 5.4.1.3 GID-2670253 RETRIEVAL EXCEPTION (SR0510.3.2.2)

In case alarms from the DCS cannot be retrieved, the system automatically records a system-triggered exception:

Representation of the exception:

- <Exception text>  
(taken from **Retrieval exception (SR0510.8.6)** process parameter ([GID-2670249](#)))  
Cannot connect to the DCS.
- Example:  
Issues was alarm retrieval.  
Cannot connect to the DCS.

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Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

#### 5.4.1.4 GID-2670254 RETRIEVAL EXCEPTION - LOGIC (SR0510.3.2.2.1)

- Trigger: Alarms could not be retrieved from the DCS
- Postcondition: Exception is recorded

Step	#	Description
Retrieval error occurs	10	Phase automatically records exception without user interaction.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

#### 5.4.1.5 GID-2670255 RETRIEVAL EXCEPTION - RESUME (SR0510.3.2.2.2)

- Trigger: Alarms can be retrieved from the DCS
- Postcondition: Comment is added to the corresponding exception

Step	#	Description
DCS Adapter is available again	10	As soon as the phase is able to retrieve alarms again, the system adds a comment to the exception (The connection to the DCS has been re-established.).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

#### 5.4.1.6 GID-2670256 POST-ETO ALARMS EXCEPTION (SR0510.3.2.3)

In case new alarms were retrieved from the DCS after the ETO template has been removed, the system cannot fire triggers and automatically records a system-triggered exception:

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

#### 5.4.1.7 REPRESENTATION OF THE EXCEPTION:

- <Exception text>  
(taken from **Post-ETO alarms exception (SR0510.8.7)** process parameter ([GID-2670250](#)))  
One or more DCS alarms have occurred after the last retrieval.
  - Example:  
Alarms without trigger processing.  
One or more DCS alarms have occurred after the last retrieval.

#### 5.4.1.8 GID-2670258 POST-ETO ALARMS EXCEPTION - LOGIC (SR0510.3.2.3.1)

- Trigger: Alarms were retrieved after the removal of the ETO template
- Postcondition: Exception is recorded

Step	#	Description
Alarms retrieved after removal of ETO template	10	Phase automatically records exception without user interaction and adds the affected alarms as comments to the exception.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

### 5.5 Output Variables

The following output variables are available to reference the phase's output.

#### 5.5.1 *Instance count (Framework capability)*

- Data type: Long
- Usage: The output variable provides the count of the number of instances the phase has been processed, for example in a loop. The count is also increased when the phase is skipped from an operator's perspective, since the phase is still executed, but as a hidden phase.  
The count variable of a phase that has not been executed provides 0 as output value.

#### 5.5.2 *Start time (Framework capability)*

- Data type: Timestamp
- Usage: The output variable provides the start time of the phase.

#### 5.5.3 *Completion time (Framework capability)*

- Data type: Timestamp
- Usage: The output variable provides the completion time of the phase.

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#### **5.5.4 Identifier (*Framework capability*)**

- Data type: String
- Usage: The output variable provides the identifier of the phase.

### **5.6 Configuration Keys (SR0510.11+)**

The following configuration keys are available to configure the phase's behavior.

#### **5.6.1 GID-2668734 Message broker URL (SR0510.11.1)**

- Phase/DCS/DCSMessagingBrokerURL
- **Type:** String
- **Value:** tcp://<hostname>:<port>
- **Description:** Specifies the URL of the messaging server used for DCS communication. Replace <hostname> with the name of the host to be used and <port> with the port number of the host to be used.  
If no value is set, the URL defined in the PharmaSuite **MessageBrokerURL** configuration key is used.
- **Evaluated:** When a DCS phase communicates with a DCS.
- **Range:** N/A

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

#### **5.6.2 GID-2668735 Messaging timeout (SR0510.11.2)**

- Phase/DCS/DCSMessagingTimeout
- **Type:** Long
- Value: 2
- **Description:** The messaging timeout for DCS communication in seconds and the time how long a produced DCS message shall be retained by the messaging system after it has been dispatched.  
If no value is set, the timeout defined in the PharmaSuite **MessagingTimeout** configuration key is used (converted into seconds).
- **Evaluated:** When a DCS phase communicates with a DCS.
- **Range:** N/A

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

## 6 Set Order Context Phase (SR0530+)

The **Set order context** phase allows an operator to set an order context on a DCS.

An example use case is:

- Providing an order context for processing the order on an automation system  
Based on an existing master recipe, batch, and order, the phase allows to process the order on a DCS.

Different phase modes enable the usage in various situations that can occur during processing:

- In the **Manual completion** mode, the operator manually triggers to set the order context.
- In the **Automatic completion** mode, the phase sets the order context and is completed automatically without any operator interaction.

The DCS, batch, master recipe, and order ID are stored in the batch record, thereby becoming available for documentation purposes in the sub-report and batch report ([\(GID-2670250\)](#) ([\(GID-2667696\)](#))

Anomalies that occur during processing are covered by the phase exception handling (come back link) (e.g. re-send order context).

After completion the phase displays the order with its data in the Execution Window.

The Navigator displays the name of the current unit procedure.

Set the order context on the DCS.

DCS name:	JavaDCSMock	Batch ID:	BX694			
Master recipe ID:	ID_SRTD-100-01 [1]	Order ID:	ID_SRTD-002			
Material ID:	D130-01	Set 				
MFC pos.	Material ID	Quantity	UoM	Allocated batches	Order step	MFC type
140	D003-04	10.0	g		ID_SRTD-002-Automated Tableting Run	Process input
150	D005-04	20.0	g		ID_SRTD-002-Automated Tableting Run	Process input
160	D130-01	1,000.0	g		ID_SRTD-002-Automated Tableting Run	Process input
170	D130-01	1,010.0	g		ID_SRTD-002-Automated Tableting Run	Process output

Context not set yet  

Figure 5: Set order context during execution

### 6.1 Layout

The phase provides individual layouts for its representation during execution ([\(GID-2432390\)](#), in the Navigator ([\(GID-2432391\)](#), and in the sub-report ([\(GID-2432394\)](#)).

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### **6.1.1 Representation during Execution (SR0530.1+)**

The representation during execution depends on the phase mode.

#### **6.1.1.1 GID-2670259 PREVIEW MODE (SR0530.1.1)**

1. <Instruction text>  
(taken from **Instruction (SR0530.8.1)** process parameter ([GID-2670276](#)))
2. DCS name: <logical name>  
(taken from **DCS (SR0530.8.3)** process parameter ([GID-2670278](#)))
3. Batch ID: <identifier>  
Master recipe ID: <identifier>  
Order ID: <identifier>  
Material ID: <identifier>  
(taken from the order context of the phase)
4. **Set** button (disabled).
5. List of MFC positions of the order (Table of MFC positions (SR0530.1.4) ([GID-2670261](#)))
  - Empty table.
6. Request-specific information:
  - Context not set yet.
7. **Confirm** button (disabled).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	Medium
MES-Compliance: 21 CFR Part 11 relevance	No

#### **6.1.1.2 GID-2670260 ACTIVE MODE (SR0530.1.2)**

1. Instruction table panel and/or instruction link panel  
(only if an instruction table and/or instruction link is defined for the phase)
2. <Instruction text>  
(taken from **Instruction (SR0530.8.1)** process parameter ([GID-2670276](#)))
3. DCS name: <logical name>  
(taken from **DCS (SR0530.8.3)** process parameter ([GID-2670278](#)))
4. Batch ID: <identifier>  
Master recipe ID: <identifier>  
Order ID: <identifier>  
Material ID: <identifier>  
(taken from the order context of the phase)
5. **Set** button (disabled after a set order context request has been sent).

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- 6. List of MFC positions of the order (Table of MFC positions (SR0530.1.4) ([GID-2670261](#)))
- 7. Request-specific information:
  - Context not set yet.  
Initial message.
  - Context set successfully (<timestamp>  
Context has been set with the **Set** button or the **Re-send order context (SR0530.3.1.2)** user-triggered exception ([GID-2670283](#)).
  - Context set manually (<timestamp>  
Context has been set with the **Set order context manually (SR0530.3.1.1)** user-triggered exception ([GID-2670281](#)).
  - Setting context failed.  
Context could not be set with the **Set** button or the **Re-send order context (SR0530.3.1.2)** user-triggered exception ([GID-2670283](#)).
- 8. **Confirm** button.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

#### 6.1.1.3 GID-2670261 TABLE OF MFC POSITIONS (SR0530.1.4)

Data available per MFC position (taken from the order context of the phase):

- MFC position
- Material ID
- [Planned] Quantity
- UoM
- Allocated batches
- Order step
- MFC type

In case the recipe structure contains selection branches (XOR) on unit procedure level and MFC-relevant material parameters, the table lists the MFC positions of all unit procedures.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

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#### **6.1.1.4 GID-2670262 COMPLETED MODE (SR0530.1.3)**

1. Instruction table panel and/or instruction link panel  
(only if an instruction table and/or instruction link is defined for the phase)
2. <Instruction text>  
(taken from **Instruction (SR0530.8.1)** process parameter ([GID-2670276](#)))
3. DCS name: <logical name>  
(taken from **DCS (SR0530.8.3)** process parameter ([GID-2670278](#)))
4. Batch ID: <identifier>  
Master recipe ID: <identifier>  
Order ID: <identifier>  
Material ID: <identifier>  
(taken from the order context of the phase)
5. List of MFC positions of the order (Table of MFC positions (SR0530.1.4) ([GID-2670261](#)))
6. Request-specific information:
  - Context set successfully (<timestamp>)
  - Context set manually (<timestamp>)
7. **Set** button (disabled).
8. **Confirm** button (completed).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

#### **6.1.2 Representation in Navigator (SR0530.4+)**

The Navigator provides the following details:

##### **6.1.2.1 PHASE COLUMN (FRAMEWORK CAPABILITY)**

- <Phase name>
  - Example:  
Send order details

##### **6.1.2.2 GID-2670264 INFORMATION COLUMN (SR0530.4.1)**

- <Order ID>
  - Example: ID-SRTD-025

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	Medium
MES-Compliance: 21 CFR Part 11 relevance	No

#### 6.1.2.3 ACTION COLUMN

There are no phase-specific actions available.

#### 6.1.3 *Representation in Sub-report (SR0530.5+)*

The sub-report contains the following information:

##### 6.1.3.1 COMMON SUB-REPORT ELEMENTS (FRAMEWORK CAPABILITY)

- <Start time>
- <Completion time>
- <Unit procedure> / <operation> / <phase>
- <Work center> / <station> / <device> - <phase completion user>

##### 6.1.3.2 GID-2670267 SUB-REPORT ELEMENTS (SR0530.5.1)

- Instruction table panel and/or instruction link panel  
(only if an instruction table and/or instruction link is defined for the phase)
- Instruction text
- DCS name: <logical name>  
Batch ID: <identifier>  
Master recipe ID: <identifier>  
Order ID: <identifier>  
Material ID: <identifier>
- Request-specific information:
  - Context set successfully (<timestamp>)
  - Context set manually (<timestamp>)
  - List of MFC positions of the order
- MFC position
- Material ID
- [Planned] Quantity
- UoM
- Allocated batches
- Order step
- MFC type

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Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

## 6.2 Business Logic (SR0530.2+)

The phase implements the following business logic.

### 6.2.1 Phase Mode

Business logic related to phase modes.

#### 6.2.1.1 GID-2670268 MANUAL COMPLETION MODE (SR0530.2.1)

- Function: **Manual completion** mode of phase
- Type: Phase mode
- Trigger: Phase becomes active
- Postcondition: Phase is active

Step	#	Description
Phase activation	10	Phase displays its user interface according to the <b>Active mode (SR0530.1.2)</b> layout ( <a href="#">GID-2670260</a> ) ( <a href="#">GID-2670260</a> )
Operator taps Set button	20	Phase sets the order context on the DCS, see <b>Send order context (SR0530.2.3)</b> function ( <a href="#">GID-2670270</a> ).
Phase completion	30	See <b>Confirm phase (SR0530.2.4)</b> function ( <a href="#">GID-2670271</a> ).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

#### 6.2.1.2 GID-2670269 AUTOMATIC COMPLETION MODE (SR0530.2.2)

- Function: **Automatic completion** mode of phase
- Type: Phase mode
- Trigger: Phase becomes active
- Postcondition: Phase is active

- Set Order Context Phase (SR0530+)

Step	#	Description
Phase activation	10	Phase displays its user interface according to the <b>Active mode (SR0530.1.2)</b> layout ( <a href="#">GID-2670260</a> ).
Phase sets order context	20	<p>See <b>Send order context (SR0530.2.3)</b> function (<a href="#">GID-2670270</a>).</p> <ul style="list-style-type: none"> <li>▪ If no error has occurred, continue with the <b>Confirm phase (SR0530.2.4)</b> function (<a href="#">GID-2670271</a>)</li> <li>▪ If an error has occurred, phase must be completed manually. See <b>Manual completion (SR0530.2.1)</b> mode (<a href="#">GID-2670268</a>).</li> </ul>

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

## 6.2.2 Main Path

Business logic related to the main path:

### 6.2.2.1 GID-2670270 SEND ORDER CONTEXT (SR0530.2.3)

- Function: Request to send the order context
- Type: Main path
- Trigger: Operator sends order context or **Automatic completion (SR0530.2.2)** mode (GID-2430377) is active
- Postcondition: Phase is active

Step	#	Description
Phase sets order context	10	Phase sets the order context on the DCS and disables the <b>Set</b> button.
	20.1	<p>If an error has occurred, phase displays the <b>Set order context error (SR0530.3.6.1)</b> error message (<a href="#">GID-2668748</a>) (<a href="#">GID-2668748</a>)</p> <p>Continue with the <b>Re-send order context (SR0530.3.1.2)</b> user-triggered exception (<a href="#">GID-2670283</a>) or the <b>Set order context manually (SR0530.3.1.1)</b> user-triggered exception (<a href="#">GID-2670281</a>).</p> <p>Phase can be completed with the <b>Confirm phase (SR0530.2.4)</b> function (<a href="#">GID-2670271</a>).</p>
	20.2	If no error has occurred, continue with the <b>Confirm phase (SR0530.2.4)</b> function ( <a href="#">GID-2670271</a> ).

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Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

#### 6.2.2.2 GID-2670271 CONFIRM PHASE (SR0530.2.4)

- Function: Completion of phase
- Type: Main path
- Trigger: Operator confirms phase or **Automatic completion (SR0530.2.2)** mode ([GID-2670269](#)) is active
- Postcondition: Phase is completed

Step	#	Description
In <b>Manual completion (SR0530.2.1)</b> mode ( <a href="#">GID-2670268</a> ): Operator confirms phase	10	Operator confirms that the order context was set.
Phase performs completion checks	20	If the order context has not been set, phase displays the <b>No order context set (SR0530.3.6.2)</b> error message ( <a href="#">GID-2668749</a> ). The phase cannot be completed. Continue with the <b>Set order context manually (SR0530.3.1.1)</b> user-triggered exception ( <a href="#">GID-2670281</a> ).
Phase completion	30	Phase is completed.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

- Set Order Context Phase (SR0530+)
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## 6.3 Process Parameters (SR0530.8+)

The following process parameters define the behavior of the phase.

### 6.3.1 *Instruction Table-specific Parameters*

#### 6.3.1.1 INSTRUCTION TABLE DEFINITION (FRAMEWORK CAPABILITY)

Attribute	Type	Comment
Table layout	Choice list	Defines the layout of the instruction table holding the instruction texts. Available settings: <b>1 column</b> , <b>2 columns</b> , <b>3 columns</b> , <b>4 columns</b> , <b>5 columns</b> . Default setting: <b>1 column</b> .
First column narrow	Boolean	Defines if the first column of the table shall be narrow.
Show all borders	Boolean	Defines if the borders of the table shall be visible.

#### 6.3.1.2 INSTRUCTION TABLE TEXT (FRAMEWORK CAPABILITY)

Attribute	Type	Comment
Column 1	HTML text	Instruction text to be displayed in a column.
Column 2	HTML text	<b>Restriction:</b> Maximum length is 2000 characters (including HTML tags).
Column 3	HTML text	
Column 4	HTML text	
Column 5	HTML text	

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### **6.3.2 Instruction Link-specific Parameters**

#### **6.3.2.1 INSTRUCTION TEXT WITH LINKS (FRAMEWORK CAPABILITY)**

Attribute	Type	Comment
Instruction text	HTML text	<p>Instruction text to be displayed.</p> <p>For any text enclosed in curly brackets you can define a hyperlink with the <b>Instruction link definition</b> process parameter (<a href="#">GID-2670275</a>)</p> <p>Example: Refer to {SOP1270} for guidance.</p> <p>Maximum length is 2000 characters (including HTML tags).</p>

#### **6.3.2.2 INSTRUCTION LINK DEFINITION (FRAMEWORK CAPABILITY)**

Attribute	Type	Comment
Link text	Text	<p>Text to be used as link.</p> <p>For any text enclosed in curly brackets within the instruction text you can define a link with the <b>Link URL</b> attribute.</p> <p>Including the brackets in the link text is optional.</p> <p>Maximum length is 80 characters.</p>
Link URL	Text	<p>URL of the file to be displayed. The link opens the external application assigned to the file type by the operating system.</p> <p>Maximum length is 256 characters.</p>

- Set Order Context Phase (SR0530+)

### 6.3.3 Basic Parameters

#### 6.3.3.1 GID-2670276 INSTRUCTION (SR0530.8.1)

Attribute	Type	Comment
Text	HTML text	Instruction text to be displayed. <b>Restriction:</b> Maximum length is 4000 characters (including HTML tags).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

#### 6.3.3.2 GID-2670277 MODE (SR0530.8.2)

Attribute	Type	Comment
Mode	Choice list	Defines the processing mode. <b>Manual completion</b> (default): Operator confirms the phase. <b>Automatic completion</b> : Phase is automatically completed after the order context has been set successfully on the DCS.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

#### 6.3.3.3 GID-2670278 DCS (SR0530.8.3)

Attribute	Type	Comment
Name	String	Logical name of the DCS to be used. The available entries correspond to the entries in the <b>DCSNames</b> list. Default setting: First entry in the list. Maximum length is 255 characters.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

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#### **6.3.4 Configuration of User-triggered Exceptions**

##### **6.3.4.1 GID-2670279 SET ORDER CONTEXT MANUALLY (SR0530.8.4)**

Attribute	Type	Comment
Risk assessment	Choice list	<p>Defines the risk level of the exception and thus controls the related signature privilege.</p> <p>Available settings: <b>None</b>, <b>Low</b>, <b>Low (mandatory comment)</b>, <b>Medium</b>, <b>Medium (mandatory comment)</b>, <b>High</b>, <b>High (mandatory comment)</b>.</p> <p>Default setting: <b>High</b>, defined by the <b>DefaultRiskClassForPhaseProcessParameter</b> configuration key.</p>
Exception text	Text	<p>Defines the exception description used during exception handling and within the batch record.</p> <p>Maximum length is 256 characters.</p>

See also **Set order context manually (SR0530.3.1.1)** user-triggered exception ([\(GID-2670281\)](#))

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

##### **6.3.4.2 GID-2670280 RE-SEND ORDER CONTEXT (SR0530.8.5)**

Attribute	Type	Comment
Risk assessment	Choice list	<p>Defines the risk level of the exception and thus controls the related signature privilege.</p> <p>Available settings: <b>None</b>, <b>Low</b>, <b>Low (mandatory comment)</b>, <b>Medium</b>, <b>Medium (mandatory comment)</b>, <b>High</b>, <b>High (mandatory comment)</b>.</p> <p>Default setting: <b>High</b>, defined by the <b>DefaultRiskClassForPhaseProcessParameter</b> configuration key.</p>

- Set Order Context Phase (SR0530+)
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Attribute	Type	Comment
Exception text	Text	Defines the exception description used during exception handling and within the batch record. Maximum length is 256 characters.

See also **Re-send order context (SR0530.3.1.2)** user-triggered exception [\(GID-2670283\)](#).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

## 6.4 Exceptions (SR0530.3+)

The phase supports user-defined, user-triggered [\(GID-2668746\)](#), system-triggered [\(GID-2668745\)](#), and post-completion exceptions [\(GID-2668747\)](#) and their configuration by means of process parameters (come back link).

User-defined exceptions cannot be configured by process parameters since they are provided by the framework and independent of phases.

### 6.4.1 System-triggered Exceptions

There are no system-triggered exceptions available.

### 6.4.2 User-triggered Exceptions (SR0530.3.1+)

A user-triggered exception is represented in the list of available user-triggered exceptions in the Exception Window, as the description of the exception, and in the batch report.

The following user-triggered exceptions are available.

#### 6.4.2.1 GID-2670281 SET ORDER CONTEXT MANUALLY (SR0530.3.1.1)

The **Set order context manually** exception allows an operator to set the order context manually on the DCS.

Representation of the exception:

- Instruction:  
Set the order context manually.  
**Confirm** button.
- Exception text:  
<Exception text>  
(taken from **Set order context manually (SR0530.8.4)** process parameter [\(GID-2670279\)](#))  
Set manually: <order ID>

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- Example:  
Order context set manually  
Set manually: ID-SRTD-025

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

#### 6.4.2.2 GID-2670282 SET ORDER CONTEXT MANUALLY - LOGIC (SR0530.3.1.1.1)

- Trigger: Exception is selected
- Postcondition: Order context is set on the DCS

Step	#	Description
Operator confirms and signs exception	10	Phase records the exception, updates request-specific information in the <b>Active mode (SR0530.1.2)</b> layout ( <a href="#">GID-2670260</a> ), and disables the <b>Set</b> button in the <b>Active mode (SR0530.1.2)</b> layout ( <a href="#">GID-2670260</a> ).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

#### 6.4.2.3 GID-2670283 RE-SEND ORDER CONTEXT (SR0530.3.1.2)

The **Re-send order context** exception allows an operator to re-send the request to set the order context to the DCS.

Representation of the exception:

- Instruction:  
Re-send the order context.  
**Confirm** button.
- Exception text:  
<Exception text>  
(taken from **Re-send order context (SR0530.8.5)** process parameter ([GID-2670280](#)))  
Re-sent: <order ID>
  - Example:  
Order context re-sent.  
Re-sent: ID-SRTD-025

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

#### 6.4.2.4 GID-2670284 RE-SEND ORDER CONTEXT - LOGIC (SR0530.3.1.2.1)

- Trigger: Exception is selected
- Postcondition: Order context is set on the DCS

Step	#	Description
Operator confirms and signs exception	10	Phase records the exception and sends a request to the DCS.
Phase receives feedback from the DCS	20	Phase adds a comment with the result of re-sending the order context (success or failure) to the exception, updates request-specific information in the <b>Active mode (SR0530.1.2)</b> layout ( <a href="#">GID-2670260</a> ), and disables the <b>Set</b> button in the <b>Active mode (SR0530.1.2)</b> layout ( <a href="#">GID-2670260</a> ). If the setting of the order context fails, the phase cannot be completed (see <b>Confirm phase (SR0530.2.4)</b> function ( <a href="#">GID-2670271</a> )).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

#### 6.4.3 Post-completion Exceptions

There are no post-completion exceptions available.

#### 6.5 Information Messages

There are no information messages available.

#### 6.6 Questions

There are no questions available.

#### 6.7 Decisions

There are no decisions available.

#### 6.8 Error Messages (SR0530.3.6+)

Error messages are represented in an error message dialog containing a message type-specific icon, the error message, and an **OK** button.

The following error messages are available to inform the operator about error conditions.

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#### **6.8.1 GID-2668748 Set order context error (SR0530.3.6.1)**

UI text	Comment
The Set order context action was not successful. Please set the values manually.	Message pack: PhaseSetOrderContext<version> Message ID: RequestSentError_message

The **Details** button provides access to more specific technical information.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

#### **6.8.2 GID-2668749 Order context not set (SR0530.3.6.2)**

UI text	Comment
Cannot confirm. The order context has not been set yet. Please set the order context first.	Message pack: PhaseSetOrderContext<version> Message ID: RequestNotProcessed_ErrorMsg

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

### **6.9 Output Variables (SR0530.9+)**

The following output variables are available to reference the phase's output.

#### **6.9.1 Instance count (Framework capability)**

- Data type: Long
- Usage: The output variable provides the count of the number of instances the phase has been processed, for example in a loop. The count is also increased when the phase is skipped from an operator's perspective, since the phase is still executed, but as a hidden phase.  
The count variable of a phase that has not been executed provides 0 as output value.

### **6.9.2 Start time (*Framework capability*)**

- Data type: Timestamp
- Usage: The output variable provides the start time of the phase.

### **6.9.3 Completion time (*Framework capability*)**

- Data type: Timestamp
- Usage: The output variable provides the completion time of the phase.

### **6.9.4 Identifier (*Framework capability*)**

- Data type: String
- Usage: The output variable provides the identifier of the phase.

## **6.10 Configuration Keys (SR0530.11+)**

The following configuration keys are available to configure the phase's behavior.

### **6.10.1 GID-2668754 Message broker URL (SR0530.11.1)**

#### **Phase/DCS/DCSMessagesBrokerURL**

- **Type:** String
- **Value:** tcp://<hostname>:<port>
- **Description:** Specifies the URL of the messaging server used for DCS communication. Replace <hostname> with the name of the host to be used and <port> with the port number of the host to be used.  
If no value is set, the URL defined in the PharmaSuite **MessageBrokerURL** configuration key is used.
- **Evaluated:** When a DCS phase communicates with a DCS.
- **Range:** N/A

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

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#### **6.10.2 GID-2668755 Messaging timeout (SR0530.11.2)**

- Phase/DCS/DCSMessagingTimeout
- **Type:** Long
- Value: 2
- **Description:** The messaging timeout for DCS communication in seconds and the time how long a produced DCS message shall be retained by the messaging system after it has been dispatched.  
If no value is set, the timeout defined in the PharmaSuite **MessagingTimeout** configuration key is used (converted into seconds).
- **Evaluated:** When a DCS phase communicates with a DCS.
- **Range:** N/A

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

## 7 Show Consumed Material Phase (SR0535+)

([GID-2667707](#)) The **Show consumed material** phase allows an operator to display material consumption data provided by a DCS.

An example use case is:

- Including data on material that was consumed on an automation system in the batch report created by the MES.

The material-, batch-, and consumption-related data is stored in the batch record, thereby becoming available for documentation purposes in the sub-report and batch report ([GID-2668758](#)).

Anomalies that occur during processing are covered by the phase exception handling link (e.g. add consumption).

After completion the phase displays the consumption-related data of a material with its data in the Execution Window.

The Navigator displays the number of consumption entries.

Confirm consumption data from the DCS.								
MFC pos.	Material	Batch ID / subplot ID	Planned	Recorded	DCS execution timestamp	DCS performer	Sender	Sublot consumed
140	D003-04 / Ethanol 96 %	N/A	10.0 g	10.0 g				
		BX866 / SL00000472		10.0 g	02/13/2023 12:33:14 PM IST	Raita, Oupah (oraita)	MES	<input checked="" type="checkbox"/>
150	D005-04 / Talc	N/A	20.0 g	0.0 g				
160	D130-01 / Sonolin 100 mg premix	N/A	1,000.0 g	0.0 g				

Figure 6: Show consumed material during execution

### 7.1 Layout

The phase provides individual layouts for its representation during execution ([GID-2668756](#)), in the Navigator ([GID-2668757](#)), and in the sub-report ([GID-2668758](#)).

#### 7.1.1 Representation during Execution (SR0535.1+)

The representation during execution depends on the phase mode.

##### 7.1.1.1 GID-2670285 PREVIEW MODE (SR0535.1.1)

1. <Instruction text>  
(taken from **Instruction (SR0535.8.1)** process parameter ([GID-2670667](#)))
2. **Refresh** button (disabled)

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3. List of MFC positions providing consumption data (Table of MFC positions (SR0535.1.4) ([GID-2670287](#)))  
(taken from material input parameters (SR0535.6.1) ([GID-2670659](#)))
4. **Confirm** button (disabled).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	Medium
MES-Compliance: 21 CFR Part 11 relevance	No

#### 7.1.1.2 GID-2670286 ACTIVE MODE (SR0535.1.2)

1. Instruction table panel and/or instruction link panel  
(only if an instruction table and/or instruction link is defined for the phase)
2. <Instruction text>  
(taken from **Instruction** (SR0535.8.1) process parameter ([GID-2670667](#)))
3. **Refresh** button
4. List of MFC positions providing consumption data (Table of MFC positions (SR0535.1.4) ([GID-2670287](#)))  
(taken from material input parameters (SR0535.6.1) ([GID-2670659](#)))
5. **Confirm** button.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

#### 7.1.1.3 GID-2670287 TABLE OF MFC POSITIONS (SR0535.1.4)

Data available per MFC position:

- MFC position (taken from material input parameters (SR0535.6.1) ([GID-2670659](#)))
- Material [ID / short description] (taken from material input parameters (SR0535.6.1) ([GID-2670659](#)))
- Batch ID / subplot ID (provided by the DCS)
- Planned [quantity] (taken from material input parameters (SR0535.6.1) ([GID-2670659](#)))
- Recorded [quantity] (provided by the DCS)
- DCS execution timestamp (provided by the DCS)
- DCS performer (provided by the DCS)
- Sender (provided by the DCS)
- Sublot consumed (provided by the DCS)

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Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

#### 7.1.1.4 GID-2670288 COMPLETED MODE (SR0535.1.3)

1. Instruction table panel and/or instruction link panel  
(only if an instruction table and/or instruction link is defined for the phase)
2. <Instruction text>  
(taken from **Instruction (SR0535.8.1)** process parameter ([GID-2670667](#)))
3. **Refresh** button (disabled)
4. List of MFC positions providing consumption data (Table of MFC positions (SR0535.1.4) ([GID-2670287](#)))  
(taken from material input parameters (SR0535.6.1) ([GID-2670659](#)))
5. **Confirm** button (completed).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

#### 7.1.2 Representation in Navigator (SR0535.4+)

The Navigator provides the following details:

##### 7.1.2.1 GID-2670289 INFORMATION COLUMN (SR0535.4.1)

- <Number of consumption entries> consumptions
  - Example: 5 consumptions

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	Medium
MES-Compliance: 21 CFR Part 11 relevance	No

##### 7.1.2.2 PHASE COLUMN (FRAMEWORK CAPABILITY)

- <Phase name>
  - Example:  
Stearate consumptions

##### 7.1.2.3 ACTION COLUMN

- There are no phase-specific actions available.

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### **7.1.3 Representation in Sub-report (SR0535.5+)**

The sub-report contains the following information:

#### **7.1.3.1 COMMON SUB-REPORT ELEMENTS (FRAMEWORK CAPABILITY)**

- <Start time>
- <Completion time>
- <Unit procedure> / <operation> / <phase>
- <Work center> / <station> / <device> - <phase completion user>

#### **7.1.3.2 GID-2670658 SUB-REPORT ELEMENTS (SR0535.5.1)**

- Instruction table panel and/or instruction link panel  
(only if an instruction table and/or instruction link is defined for the phase)
- Instruction text
- List of MFC positions providing consumption data
  - MFC position
  - Material [ID / short description]
  - Batch ID / subplot ID
  - Planned [quantity]
  - Recorded [quantity]
  - DCS execution timestamp
  - DCS performer
  - Sender
  - Sublot consumed

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

## **7.2 Business Logic (SR0535.2+)**

The phase implements the following business logic.

#### **7.2.1 GID-2668759 Display consumption data (SR0535.2.1)**

- Function: Display the received consumption data
- Trigger: Phase becomes active and has received a consumption request from the DCS
- Postcondition: Phase is completed

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Step	#	Description
Phase activation	10	Phase displays its user interface according to the <b>Active mode (SR0535.1.2)</b> layout ( <a href="#">GID-2670286</a> ).
Operator action	20	Optional: <ul style="list-style-type: none"> <li>The Refresh button reads the consumption data again and updates the displayed data.</li> </ul>
Phase completion	30	Phase is completed.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

## 7.3 Recipe Parameters

The phase provides material input parameters as process inputs ([GID-2668760](#)) and process parameters ([GID-2668761](#)).

### 7.3.1 Process Inputs (SR0535.6+)

#### 7.3.1.1 GID-2670659 MATERIAL INPUT PARAMETERS (SR0535.6.1)

The default material input parameters are available to define for which materials consumption-related data is accepted during execution.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

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### **7.3.2 Process Parameters (SR0535.8+)**

The following process parameters define the behavior of the phase.

#### **7.3.2.1 INSTRUCTION TABLE-SPECIFIC PARAMETERS**

##### **7.3.2.1.1 INSTRUCTION TABLE DEFINITION (FRAMEWORK CAPABILITY)**

<b>Attribute</b>	<b>Type</b>	<b>Comment</b>
Table layout	Choice list	Defines the layout of the instruction table holding the instruction texts. Available settings: <b>1 column, 2 columns, 3 columns, 4 columns, 5 columns.</b> Default setting: <b>1 column.</b>
First column narrow	Boolean	Defines if the first column of the table shall be narrow.
Show all borders	Boolean	Defines if the borders of the table shall be visible.

##### **7.3.2.1.2 INSTRUCTION TABLE TEXT (FRAMEWORK CAPABILITY)**

<b>Attribute</b>	<b>Type</b>	<b>Comment</b>
Column 1	HTML text	Instruction text to be displayed in a column.
Column 2	HTML text	<b>Restriction:</b> Maximum length is 2000 characters (including HTML tags).
Column 3	HTML text	
Column 4	HTML text	
Column 5	HTML text	

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### 7.3.2.2 INSTRUCTION LINK-SPECIFIC PARAMETERS

#### 7.3.2.2.1 INSTRUCTION TEXT WITH LINKS (FRAMEWORK CAPABILITY)

Attribute	Type	Comment
Instruction text	HTML text	<p>Instruction text to be displayed.</p> <p>For any text enclosed in curly brackets you can define a hyperlink with the <b>Instruction link definition</b> process parameter (<a href="#">GID-2670665</a>).</p> <p>Example: Refer to {SOP1270} for guidance.</p> <p>Maximum length is 2000 characters (including HTML tags).</p>

#### 7.3.2.2.2 INSTRUCTION LINK DEFINITION (FRAMEWORK CAPABILITY)

Attribute	Type	Comment
Link text	Text	<p>Text to be used as link.</p> <p>For any text enclosed in curly brackets within the instruction text you can define a link with the <b>Link URL</b> attribute.</p> <p>Including the brackets in the link text is optional.</p> <p>Maximum length is 80 characters.</p>
Link URL	Text	<p>URL of the file to be displayed. The link opens the external application assigned to the file type by the operating system.</p> <p>Maximum length is 256 characters.</p>

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### 7.3.2.3 BASIC PARAMETERS

#### 7.3.2.3.1 GID-2670667 INSTRUCTION (SR0535.8.1)

Attribute	Type	Comment
Text	HTML text	Instruction text to be displayed. <b>Restriction:</b> Maximum length is 4000 characters (including HTML tags).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

### 7.3.2.4 CONFIGURATION OF USER-TRIGGERED EXCEPTIONS

#### 7.3.2.4.1 GID-2670669 REMOVE INCORRECTLY RECORDED DATA SET (SR0535.8.2)

Attribute	Type	Comment
Risk assessment	Choice list	Defines the risk level of the exception and thus controls the related signature privilege. Available settings: <b>None</b> , <b>Low</b> , <b>Low (mandatory comment)</b> , <b>Medium</b> , <b>Medium (mandatory comment)</b> , <b>High</b> , <b>High (mandatory comment)</b> . Default setting: <b>High</b> , defined by the <b>DefaultRiskClassForPhaseProcessParameter</b> configuration key.
Exception text	Text	Defines the exception description used during exception handling and within the batch record. Maximum length is 256 characters.

See also Remove incorrectly recorded data set (SR0535.3.1.1) user-triggered exception ([GID-2670671](#)).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

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#### 7.3.2.4.2 GID-2670670 ADD CONSUMPTION (SR0535.8.3)

Attribute	Type	Comment
Risk assessment	Choice list	Defines the risk level of the exception and thus controls the related signature privilege. Available settings: <b>None</b> , <b>Low</b> , <b>Low (mandatory comment)</b> , <b>Medium</b> , <b>Medium (mandatory comment)</b> , <b>High</b> , <b>High (mandatory comment)</b> . Default setting: <b>High</b> , defined by the <b>DefaultRiskClassForPhaseProcessParameter</b> configuration key.
Exception text	Text	Defines the exception description used during exception handling and within the batch record. Maximum length is 256 characters.

See also **Add consumption (SR0535.3.1.2)** user-triggered exception ([GID-2670673](#)).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

## 7.4 Exceptions (SR0535.3+)

The phase supports user-defined, user-triggered ([GID-2668763](#)), system-triggered ([GID-3345286](#)), and post-completion exceptions ([GID-2668764](#)) and their configuration by means of process parameters ([GID-2668761](#)).

User-defined exceptions cannot be configured by process parameters since they are provided by the framework and independent of phases.

### 7.4.1 System-triggered Exceptions

There are no system-triggered exceptions available.

### 7.4.2 User-triggered Exceptions (SR0535.3.1+)

A user-triggered exception is represented in the list of available user-triggered exceptions in the Exception Window, as the description of the exception, and in the batch report.

The following user-triggered exceptions are available.

#### 7.4.2.1 GID-2670671 REMOVE INCORRECTLY RECORDED DATA SET (SR0535.3.1.1)

The **Remove incorrectly recorded data set** exception allows an operator to remove the data set of an incorrectly recorded consumption message that was received from a DCS.

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Representation of the exception:

- Instruction:  
Select the incorrectly recorded data set to be removed.  
List of consumption entries available for removal (Table of MFC positions (SR0535.1.4) ([GID-2670287](#))).  
**Confirm** button.
- Exception text:  
<Exception text>  
(taken from **Remove incorrectly recorded data set (SR0535.8.2)** process parameter ([GID-2670669](#)))  
Removed data set: <MFC position>, <Material ID / short description>, <Batch ID / <Sublot ID>, <Consumed qty. with UoM>, <DCS execution timestamp>, <DCS performer>, <Sender>
  - Example:  
Data set removed.  
Removed data set: 140, D130-01 / Sonolin 100 mg premix, BX32 / SL00000639, 437.6 g, 07/24/2017 10:00:47 AM CEST, Raita, Oupah (oraita), MES

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

#### 7.4.2.2 GID-2670672 REMOVE INCORRECTLY RECORDED DATA SET - LOGIC (SR0535.3.1.1.1)

- Trigger: Exception is selected (with data set selected)
- Postcondition: Data set is removed

Step	#	Description
Operator confirms and signs exception	10	Phase records the exception and sends a removal request for the incorrectly recorded data set. If no data set has been selected, phase displays the <b>No entry selected (SR0535.3.6.1)</b> error message ( <a href="#">GID-2668765</a> ). The exception cannot be recorded.
Phase receives feedback	20	Phase adds a comment with the removal result (success or failure) to the exception. If the removal was not successful, phase displays the <b>Data set not removed (SR0535.3.6.5)</b> error message ( <a href="#">GID-2668769</a> ). If the removal was successful, phase updates the <b>Active mode (SR0535.1.2)</b> layout ( <a href="#">GID-2670286</a> ).

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Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

#### 7.4.2.3 GID-2670673 ADD CONSUMPTION (SR0535.3.1.2)

The **Add consumption** exception allows an operator to add a missing consumption entry.

Representation of the exception:

- Instruction:

Add a consumption for the selected material.

<List of MFC positions available for adding (taken from material input parameters (SR0535.6.1) ([GID-2670659](#))>

- MFC position
- Material ID
- Material short description
- [Material] Unit of measure

<Input boxes>

- Batch ID <identifier>
- Sublot ID <identifier>
- Timestamp <consumption timestamp>
- Performer <consumption performer>
- Consumed qty. <quantity>
- Consumed completely <Yes/No>

**Confirm** button.

- Exception text:

<Exception text>

(taken from **Add consumption (SR0535.8.3)** process parameter ([GID-2670670](#)))

Added consumption: <MFC position>, <Material ID / short description>, <Batch ID / <Sublot ID>, <Consumed qty. with UoM>, <DCS execution timestamp>, <DCS performer>, <Sender>, Consumed completely: <Yes/No>

- Example:

Consumption added.

Added consumption: 140, D130-01 / Sonolin 100 mg premix, BX32 / SL00000639, 437.6 g, 07/24/2017 10:00:47 AM CEST, Raita, Oupah (oraita), MES, Consumed completely: Yes

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

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#### 7.4.2.4 GID-2670674 ADD CONSUMPTION - LOGIC (SR0535.3.1.2.1)

- Trigger: Exception is selected
- Postcondition: Consumption is added

Step	#	Description
Operator triggers exception	10	Phase displays Exception Window.
Operator action	20	Operator selects MFC position/material and enters data of the consumption entry to be added.
Operator confirms exception	30	If the data entered in the input boxes is invalid, phase displays the <b>Invalid data (SR0535.3.6.2)</b> error message ( <a href="#">GID-2668766</a> ). If mandatory data is missing, phase displays the <b>Missing data (SR0535.3.6.3)</b> error message ( <a href="#">GID-2668767</a> ).
Operator signs exception	40	Phase records the exception and sends an add consumption request.
Phase receives feedback	50	Phase adds a comment with the result of adding the consumption (success or failure) to the exception. If the consumption entry could not be added, phase displays the <b>Consumption not added (SR0535.3.6.4)</b> error message ( <a href="#">GID-2668768</a> ). If the consumption entry was added successfully, phase updates the <b>Active mode (SR0535.1.2)</b> layout ( <a href="#">GID-2670286</a> ).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

#### 7.4.3 Post-completion Exceptions

There are no post-completion exceptions available.

### 7.5 Information Messages

There are no information messages available.

### 7.6 Questions

There are no questions available.

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## 7.7 Decisions

There are no decisions available.

## 7.8 Error Messages (SR0535.3.6+)

Error messages are represented in an error message dialog containing a message type-specific icon, the error message, and an **OK** button.

The following error messages are available to inform the operator about error conditions.

### 7.8.1 *GID-2668765 No entry selected (SR0535.3.6.1)*

UI text	Comment
You have to select a data set to be removed.	Message pack: PhaseShowConsMat<version> Message ID: NoEntrySelectedForRemoval_Err

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

### 7.8.2 *GID-2668766 Invalid data (SR0535.3.6.2)*

UI text	Comment
The following field contains an invalid value: <input box>	Message pack: PhaseShowConsMat<version> Message ID: InvalidFieldInEntryForAdding_Err

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

### 7.8.3 *GID-2668767 Missing data (SR0535.3.6.3)*

UI text	Comment
There is data missing in mandatory fields: <input boxes>	Message pack: PhaseShowConsMat<version> Message ID: MissingFieldsInEntryForAdding_Err

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

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#### 7.8.4 GID-2668768 Consumption not added (SR0535.3.6.4)

UI text	Comment
The consumption could not be added.	Message pack: PhaseShowConsMat<version> Message ID: Info_AddConsumption_Error

The **Details** button provides access to more specific technical information.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

#### 7.8.5 GID-2668769 Data set not removed (SR0535.3.6.5)

UI text	Comment
The incorrectly recorded data set could not be removed.	Message pack: PhaseShowConsMat<version> Message ID: Info_RemoveConsumption_Error

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

## 7.9 Output Variables (SR0535.9+)

The following output variables are available to reference the phase's output.

### 7.9.1 Instance count (Framework capability)

- Data type: Long
- Usage: The output variable provides the count of the number of instances the phase has been processed, for example in a loop. The count is also increased when the phase is skipped from an operator's perspective, since the phase is still executed, but as a hidden phase.  
The count variable of a phase that has not been executed provides 0 as output value.

### 7.9.2 Start time (Framework capability)

- Data type: Timestamp
- Usage: The output variable provides the start time of the phase.

### 7.9.3 Completion time (*Framework capability*)

- Data type: Timestamp
- Usage: The output variable provides the completion time of the phase.

### 7.9.4 Identifier (*Framework capability*)

- Data type: String
- Usage: The output variable provides the identifier of the phase.

## 7.10 Configuration Keys (SR0535.11+)

The following configuration keys are available to configure the phase's behavior.

### 7.10.1 GID-2668774 Message broker URL (SR0535.11.1)

- Phase/DCS/DCSMessagesBrokerURL
- **Type:** String
- **Value:** tcp://<hostname>:<port>
- **Description:** Specifies the URL of the messaging server used for DCS communication. Replace <hostname> with the name of the host to be used and <port> with the port number of the host to be used.  
If no value is set, the URL defined in the PharmaSuite **MessageBrokerURL** configuration key is used.
- **Evaluated:** When a DCS phase communicates with a DCS.
- **Range:** N/A

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

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#### **7.10.2 GID-2668775 Messaging timeout (SR0535.11.2)**

- Phase/DCS/DCSMessagingTimeout
- **Type:** Long
- Value: 2
- **Description:** The messaging timeout for DCS communication in seconds and the time how long a produced DCS message shall be retained by the messaging system after it has been dispatched.  
If no value is set, the timeout defined in the PharmaSuite **MessagingTimeout** configuration key is used (converted into seconds).
- **Evaluated:** When a DCS phase communicates with a DCS.
- **Range:** N/A

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

## 8 Show Produced Material Phase (SR0536+)

The **Show produced material** phase allows an operator to display material production data provided by a DCS.

An example use case is:

- Including data on material that was produced on an automation system in the batch report created by the MES.

The material-, batch-, and production-related data is stored in the batch record, thereby becoming available for documentation purposes in the sub-report and batch report ([GID-2668778](#)) ([GID-2667718](#))

Anomalies that occur during processing are covered by the phase exception handling link (e.g. correct produced material).

After completion the phase displays the production-related data of a material with its data in the Execution Window.

The Navigator displays the number of production entries.

Confirm production data from the DCS.

Material:	D130-01 / Sonolin 100 mg premix		
MFC position:	170	Batch ID:	BX310
Planned quantity:	1,010.0 g	Total recorded quantity:	1,010.0 g

**Refresh**

Sublot ID	Recorded	DCS execution timestamp	DCS performer	Sender
SL00000151	1,010.0 g	10/12/2022 07:41:33 PM IST	Raita, Oupah (oraita)	MES

**Confirm**

Figure 7: Show produced material during execution

### 8.1 Layout

The phase provides individual layouts for its representation during execution ([GID-2668776](#)), in the Navigator ([GID-2668777](#)), and in the sub-report ([GID-2668778](#)).

#### 8.1.1 Representation during Execution (SR0536.1+)

The representation during execution depends on the phase mode.

##### 8.1.1.1 GID-2670675 PREVIEW MODE (SR0536.1.1)

1. <Instruction text>  
(taken from Instruction (SR0536.8.1) process parameter ([GID-2670691](#)))

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2. Material: <identifier / short description>  
MFC position: <identifier>  
(taken from material output parameters (SR0536.7.1) ([GID-2670683](#)))  
Batch ID: <identifier>  
Planned quantity: <quantity UoM>  
Total recorded quantity: <quantity UoM>  
(taken from the order context of the phase)
3. Refresh button (disabled)
4. List of sublots providing production data (Table of sublots (SR0536.1.4) ([GID-2670677](#)))  
(taken from the order context of the phase)
5. Confirm button (disabled).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	Medium
MES-Compliance: 21 CFR Part 11 relevance	No

#### 8.1.1.2 GID-2670676 ACTIVE MODE (SR0536.1.2)

1. Instruction table panel and/or instruction link panel  
(only if an instruction table and/or instruction link is defined for the phase)
2. <Instruction text>  
(taken from **Instruction (SR0536.8.1)** process parameter ([GID-2670691](#)))
3. Material: <identifier / short description>  
MFC position: <identifier>  
(taken from material output parameters (SR0536.7.1) ([GID-2670683](#)))  
Batch ID: <identifier>  
Planned quantity: <quantity UoM>  
Total recorded quantity: <quantity UoM>  
(taken from the order context of the phase)
4. **Refresh** button
5. List of sublots providing production data (Table of sublots (SR0536.1.4) ([GID-2670677](#)))  
(taken from the order context of the phase)
6. **Confirm** button.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

### 8.1.1.3 GID-2670677 TABLE OF SUBLOTS (SR0536.1.4)

Data available per subplot:

- Sublot ID (provided by the DCS)
- Recorded [quantity] (provided by the DCS)
- DCS execution timestamp (provided by the DCS)
- DCS performer (provided by the DCS)
- Sender (provided by the DCS)

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

### 8.1.1.4 GID-2670678 COMPLETED MODE (SR0536.1.3)

1. Instruction table panel and/or instruction link panel  
(only if an instruction table and/or instruction link is defined for the phase)
2. <Instruction text>  
(taken from **Instruction (SR0536.8.1)** process parameter ([GID-2670691](#)))
3. Material: <identifier / short description>  
MFC position: <identifier>  
(taken from material output parameters (SR0536.7.1) ([GID-2670683](#)))  
Batch ID: <identifier>  
Planned quantity: <quantity UoM>  
Total recorded quantity: <quantity UoM>  
(taken from the order context of the phase)
4. **Refresh** button (disabled)
5. List of sublots providing production data (Table of sublots (SR0536.1.4) ([GID-2670677](#)))  
(taken from the order context of the phase)
6. **Confirm** button (completed).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

### 8.1.2 Representation in Navigator (SR0536.4+)

The Navigator provides the following details:

#### 8.1.2.1 GID-2670679 INFORMATION COLUMN (SR0536.4.1)

- <Number of sublots> sublots

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- Example: 5 sublots
- <Phase name>
- Example: Sonolin productions

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	Medium
MES-Compliance: 21 CFR Part 11 relevance	No

#### 8.1.2.2 ACTION COLUMN

- There are no phase-specific actions available.

#### 8.1.3 *Representation in Sub-report (SR0536.5+)*

The sub-report contains the following information:

##### 8.1.3.1 COMMON SUB-REPORT ELEMENTS (FRAMEWORK CAPABILITY)

- <Start time>
- <Completion time>
- <Unit procedure> / <operation> / <phase>
- <Work center> / <station> / <device> - <phase completion user>

##### 8.1.3.2 GID-2670682 SUB-REPORT ELEMENTS (SR0536.5.1)

- Instruction table panel and/or instruction link panel  
(only if an instruction table and/or instruction link is defined for the phase)
- Instruction text
- Material
- MFC position
- Batch ID
- Planned quantity
- Total recorded quantity
- List of sublots providing production data
  - Sublot ID
  - Recorded [quantity]
  - DCS execution timestamp
  - DCS performer
  - Sender

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

## 8.2 Business Logic (SR0536.2+)

The phase implements the following business logic.

### 8.2.1 *GID-2668779 Display production data (SR0536.2.1)*

- Function: Display the received production data
- Trigger: Phase becomes active and has received a production request from the DCS
- Postcondition: Phase is completed

Step	#	Description
Phase activation	10	Phase displays its user interface according to the <b>Active mode (SR0536.1.2)</b> layout ( <a href="#">GID-2670676</a> ).
Operator action	20	Optional: <ul style="list-style-type: none"> <li>▪ The <b>Refresh</b> button reads the production data again and updates the displayed data.</li> </ul>
Phase completion	30	Phase is completed.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

## 8.3 Recipe Parameters

The phase provides material output parameters as process outputs ([GID-2668780](#)) and process parameters ([GID-2668781](#)).

### 8.3.1 *Process Outputs (SR0536.7+)*

#### 8.3.1.1 **GID-2670683 MATERIAL OUTPUT PARAMETERS (SR0536.7.1)**

The default material output parameters are available to define for which produced material-related data is accepted during execution.

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Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

### 8.3.2 Process Parameters (SR0536.8+)

The following process parameters define the behavior of the phase.

#### 8.3.2.1 INSTRUCTION TABLE-SPECIFIC PARAMETERS

#### 8.3.2.2 INSTRUCTION TABLE DEFINITION (FRAMEWORK CAPABILITY)

Attribute	Type	Comment
Table layout	Choice list	Defines the layout of the instruction table holding the instruction texts. Available settings: <b>1 column, 2 columns, 3 columns, 4 columns, 5 columns.</b> Default setting: <b>1 column.</b>
First column narrow	Boolean	Defines if the first column of the table shall be narrow.
Show all borders	Boolean	Defines if the borders of the table shall be visible.

#### 8.3.2.3 INSTRUCTION TABLE TEXT (FRAMEWORK CAPABILITY)

Attribute	Type	Comment
Column 1	HTML text	Instruction text to be displayed in a column. <b>Restriction:</b> Maximum length is 2000 characters (including HTML tags).
Column 2	HTML text	
Column 3	HTML text	
Column 4	HTML text	
Column 5	HTML text	

#### 8.3.2.4 INSTRUCTION LINK-SPECIFIC PARAMETERS

#### 8.3.2.5 INSTRUCTION TEXT WITH LINKS (FRAMEWORK CAPABILITY)

Attribute	Type	Comment
Instruction text	HTML text	<p>Instruction text to be displayed.</p> <p>For any text enclosed in curly brackets you can define a hyperlink with the <b>Instruction link definition</b> process parameter (<a href="#">GID-2670689</a>).</p> <p>Example: Refer to {SOP1270} for guidance.</p> <p>Maximum length is 2000 characters (including HTML tags).</p>

#### 8.3.2.6 INSTRUCTION LINK DEFINITION (FRAMEWORK CAPABILITY)

Attribute	Type	Comment
Link text	Text	<p>Text to be used as link.</p> <p>For any text enclosed in curly brackets within the instruction text you can define a link with the <b>Link URL</b> attribute.</p> <p>Including the brackets in the link text is optional.</p> <p>Maximum length is 80 characters.</p>
Link URL	Text	<p>URL of the file to be displayed. The link opens the external application assigned to the file type by the operating system.</p> <p>Maximum length is 256 characters.</p>

#### 8.3.2.7 BASIC PARAMETERS

#### 8.3.2.8 GID-2670691 INSTRUCTION (SR0536.8.1)

Attribute	Type	Comment
Text	HTML text	<p>Instruction text to be displayed.</p> <p><b>Restriction:</b> Maximum length is 4000 characters (including HTML tags).</p>

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Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

### 8.3.2.9 CONFIGURATION OF USER-TRIGGERED EXCEPTIONS

#### 8.3.2.10 GID-2670693 CORRECT PRODUCED MATERIAL (SR0536.8.2)

Attribute	Type	Comment
Risk assessment	Choice list	Defines the risk level of the exception and thus controls the related signature privilege. Available settings: <b>None</b> , <b>Low</b> , <b>Low (mandatory comment)</b> , <b>Medium</b> , <b>Medium (mandatory comment)</b> , <b>High</b> , <b>High (mandatory comment)</b> . Default setting: <b>High</b> .
Exception text	Text	Defines the exception description used during exception handling and within the batch record. Maximum length is 250 characters.

See also Correct produced material (SR0536.3.1.1) user-triggered exception [\(GID-2670694\)](#).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

## 8.4 Exceptions (SR0536.3+)

The phase supports user-defined, user-triggered ([\(GID-2668783\)](#), system-triggered ([\(GID-2668782\)](#), and post-completion exceptions ([\(GID-2668784\)](#) and their configuration by means of process parameters ([\(GID-2668781\)](#))

User-defined exceptions cannot be configured by process parameters since they are provided by the framework and independent of phases.

### 8.4.1 System-triggered Exceptions

There are no system-triggered exceptions available.

#### **8.4.2 User-triggered Exceptions (SR0536.3.1+)**

A user-triggered exception is represented in the list of available user-triggered exceptions in the Exception Window, as the description of the exception, and in the batch report.

The following user-triggered exceptions are available.

##### **8.4.2.1 GID-2670694 CORRECT PRODUCED MATERIAL (SR0536.3.1.1)**

The **Correct produced material** exception allows an operator to record the addition (positive quantity) or the removal (negative quantity) of produced material based on a new or on an already existing subplot.

Representation of the exception:

- Instruction:  
Add new or correct produced material.
  - Material: <identifier / short description> (taken from material output parameters (SR0536.7.1) ([GID-2670683](#)))
  - Batch ID: <identifier> (taken from the order context of the phase)

<Input boxes>

- Sublot ID <identifier>
  - Quantity <quantity UoM>
  - Timestamp <production timestamp>
  - Performer <production timestamp>

**Confirm** button.

- Exception text:  
<Exception text>  
(taken from **Correct produced material (SR0536.8.2)** process parameter ([GID-2670693](#)))  
Added material: <Sublot ID>, <Recorded qty. with UoM>, <DCS execution timestamp>, <DCS performer>, <Sender>  
Corrected production: <Sublot ID>, <Recorded qty. with UoM>, <DCS execution timestamp>, <DCS performer>, <Sender>
  - Example:  
Produced material corrected.  
Corrected production: SL00000639, 437.6 g, 07/24/2017 10:00:47 AM CEST, Raita, Oupah (oraita), MES

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

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#### **8.4.2.2 GID-2670695 CORRECT PRODUCED MATERIAL - LOGIC (SR0536.3.1.1.1)**

- Trigger: Exception is selected (with entry selected)
- Postcondition: Production entry is corrected

Step	#	Description
Operator triggers exception	10	Phase displays Exception Window.
Operator action	20	Operator enters data to add or correct the produced material.
Operator confirms exception	30	If the data entered in the input boxes is invalid, phase displays the <b>Invalid data (SR0536.3.6.2)</b> error message ( <a href="#">GID-2668785</a> ) If mandatory data is missing, phase displays the <b>Missing data (SR0536.3.6.3)</b> error message ( <a href="#">GID-2668786</a> )
Operator signs exception	40	Phase records the exception and sends a production correction request.
Phase receives feedback	50	Phase adds a comment with the result of the correction (success or failure) to the exception. If the correction was not successful, the phase displays the <b>Correction not performed (SR0536.3.6.4)</b> error message ( <a href="#">GID-2668787</a> ). If the correction was successful, the phase updates the <b>Active mode (SR0536.1.2)</b> layout ( <a href="#">GID-2670676</a> ).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

#### **8.4.3 Post-completion Exceptions**

There are no post-completion exceptions available.

### **8.5 Information Messages**

There are no information messages available.

### **8.6 Questions**

There are no questions available.

## 8.7 Decisions

There are no decisions available.

## 8.8 Error Messages (SR0536.3.6+)

Error messages are represented in an error message dialog containing a message type-specific icon, the error message, and an **OK** button.

The following error messages are available to inform the operator about error conditions.

### 8.8.1 *GID-2668785 Invalid data (SR0536.3.6.2)*

UI text	Comment
The following field contains an invalid value: <input box>	Message pack: PhaseShowProdMat<version> Message ID: InvalidFieldInEntryForAdding_Err

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

### 8.8.2 *GID-2668786 Missing data (SR0536.3.6.3)*

UI text	Comment
There is data missing in mandatory fields: <input boxes>	Message pack: PhaseShowProdMat<version> Message ID: MissingFieldsInEntryForAdding_Err

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

### 8.8.3 *GID-2668787 Correction not performed (SR0536.3.6.4)*

UI text	Comment
The production could not be added/corrected.	Message pack: PhaseShowProdMat<version> Message ID: Info_CorrectProduction_Error

The **Details** button provides access to more specific technical information.

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Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

## 8.9 Output Variables (SR0536.9+)

The following output variables are available to reference the phase's output.

### 8.9.1 *Instance count (Framework capability)*

- Data type: Long
- Usage: The output variable provides the count of the number of instances the phase has been processed, for example in a loop. The count is also increased when the phase is skipped from an operator's perspective, since the phase is still executed, but as a hidden phase.  
The count variable of a phase that has not been executed provides 0 as output value.

### 8.9.2 *Start time (Framework capability)*

- Data type: Timestamp
- Usage: The output variable provides the start time of the phase.

### 8.9.3 *Completion time (Framework capability)*

- Data type: Timestamp
- Usage: The output variable provides the completion time of the phase.

### 8.9.4 *Identifier (Framework capability)*

- Data type: String
- Usage: The output variable provides the identifier of the phase.

## 8.10 Configuration Keys (SR0536.11+)

The following configuration keys are available to configure the phase's behavior.

### **8.10.1 GID-2668792 Message broker URL (SR0536.11.1)**

- Phase/DCS/DCSMessagingBrokerURL
- **Type:** String
- **Value:** tcp://<hostname>:<port>
- **Description:** Specifies the URL of the messaging server used for DCS communication. Replace <hostname> with the name of the host to be used and <port> with the port number of the host to be used.  
If no value is set, the URL defined in the PharmaSuite **MessageBrokerURL** configuration key is used.
- **Evaluated:** When a DCS phase communicates with a DCS.
- **Range:** N/A

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

### **8.10.2 GID-2668793 Messaging timeout (SR0536.11.2)**

- Phase/DCS/DCSMessagingTimeout
- **Type:** Long
- **Value:** 2
- **Description:** The messaging timeout for DCS communication in seconds and the time how long a produced DCS message shall be retained by the messaging system after it has been dispatched.  
If no value is set, the timeout defined in the PharmaSuite **MessagingTimeout** configuration key is used (converted into seconds).
- **Evaluated:** When a DCS phase communicates with a DCS.
- **Range:** N/A

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

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## 9 Wait for Event (OES) Phase (SR0540+)

The **Wait for event (OES)** phase waits for an event from a DCS and allows to automatically synchronize an operation that runs on the OE server and the DCS or an operator-run operation.

In case the **Send event (SR0550+)** phase ([GID-2667743](#)) or a DCS runs in the asynchronous mode, it is not necessary that the targeted **Wait for event** phase is already running.

Example use cases are:

- Receive a message from an automation system  
A process has reached a certain stage on the automation system and the MES can continue with this process.
- Remind the operator of a task  
After the operator has verified that a manufacturing step was completed, the operator must receive a reminder after a defined period of time to proceed with a further procedural step.  
This example makes use of the **Time-based trigger (SR0400+)** phase (see "Functional Requirement Specification IPC Phases" [A5] ([GID-2667746](#))).

The timestamp when the message was received, the message identifier, and the information whether the wait process was aborted or not is stored in the batch record, thereby becoming available for documentation purposes in the sub-report and batch report ([GID-2668796](#)).

Anomalies that occur during processing are covered by the phase exception handling ([GID-2667729](#)) (e.g. abort wait).

### 9.1 Layout

The phase provides a layout for its representation in the sub-report ([GID-2668796](#)).

#### 9.1.1 Representation during Execution

As a server-run phase, the phase has no graphical representation (UI).

#### 9.1.2 Representation in Navigator

As a server-run phase, the phase is not visible in the Navigator.

#### 9.1.3 Representation in Sub-report (SR0540.5+)

The sub-report contains the following information:

##### 9.1.3.1 COMMON SUB-REPORT ELEMENTS (FRAMEWORK CAPABILITY)

- <Start time>
- <Completion time>
- <Unit procedure> / <operation> / <phase>

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- <Work center> / <station> / <device> - <phase completion user>

For phases running on a server, the phase completion-user corresponds to the system.

#### 9.1.3.2 GID-2670697 SUB-REPORT ELEMENTS (SR0540.5.1)

- Timestamp when the message was received
- Identifier of the received message
- Aborted: Yes/No

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

## 9.2 Business Logic (SR0540.2+)

The phase implements the following business logic.

#### 9.2.1 GID-2668797 Wait for event (SR0540.2.1)

- Function: Phase waits for event message
- Trigger: Phase becomes active
- Postcondition: Phase is completed

Step	#	Description
Phase activation	10	Phase waits for an event message with the identifier as defined with the <b>Event message (SR0540.8.1)</b> process parameter ( <a href="#">GID-2670698</a> ) or for an abort event message.
Phase receives message	20	<p>Phase processes the received message.</p> <ul style="list-style-type: none"> <li>▪ Request from the DCS to synchronize between the DCS and the order of the phase.</li> </ul> <p>OR</p> <ul style="list-style-type: none"> <li>▪ Request from the <b>Send event (SR0550+)</b> phase (<a href="#">GID-2667743</a>) to synchronize between the phases during processing of the order of the phases.</li> </ul> <p>In case the <b>Send event (SR0550+)</b> phase (<a href="#">GID-2667743</a>) runs in the asynchronous mode and the timeout period of a sent event message has elapsed, there is no event message to be processed.</p> <p>OR</p> <ul style="list-style-type: none"> <li>▪ Broadcast from the <b>Send event (SR0550+)</b> phase (<a href="#">GID-2667743</a>) of the same unit procedure to abort the wait process. Phase creates the <b>Abort Wait (SR0540.3.2.1)</b> system-triggered exception (<a href="#">GID-2670700</a>)</li> </ul>

- Wait for Event (OES) Phase (SR0540+)
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Step	#	Description
Phase completion	30	Phase sets the <b>Wait aborted (SR0540.9.1)</b> output variable <a href="#">(GID-2668805)</a> . Phase is completed.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

## 9.3 Process Parameters (SR0540.8+)

The following process parameters define the behavior of the phase.

### 9.3.1 Basic Parameters

#### 9.3.1.1 GID-2670698 EVENT MESSAGE (SR0540.8.1)

Attribute	Type	Comment
Identifier	String	Identifier of the message to be received from the DCS or the <b>Send event (SR0550+)</b> phase <a href="#">(GID-2667743)</a> . Maximum length is 80 characters.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

### 9.3.2 Configuration of System-triggered Exceptions

#### 9.3.2.1 GID-2670699 ABORT WAIT (SR0540.8.2)

Attribute	Type	Comment
Risk assessment	Choice list	Defines the risk level of the exception. Since there is no operator interaction for the exception, it is not linked to a signature privilege. Available settings: <b>None</b> , <b>Low</b> , <b>Low (mandatory comment)</b> , <b>Medium</b> , <b>Medium (mandatory comment)</b> , <b>High</b> , <b>High (mandatory comment)</b> . Default setting: <b>High</b> .

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Attribute	Type	Comment
Exception text	Text	Defines the exception description used during exception handling and within the batch record. Maximum length is 250 characters.

See also **Abort wait (SR0540.3.2.1)** system-triggered exception ([GID-2670700](#)).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

## 9.4 Exceptions (SR0540.3+)

The phase supports system-triggered exceptions ([GID-2667729](#)) and their configuration by means of process parameters ([GID-2667728](#)).

### 9.4.1 System-triggered Exceptions (SR0540.3.2+)

A system-triggered exception of a server-run phase is automatically recorded in the batch report without any user interaction.

The following system-triggered exceptions are available.

#### 9.4.1.1 GID-2670700 ABORT WAIT (SR0540.3.2.1)

In case the phase receives a broadcast message from the **Send event (SR0550+)** phase ([GID-2667743](#)) to abort the wait process, the system automatically records a system-triggered exception.

Representation of the exception:

- <Exception text>  
(taken from **Abort wait (SR0540.8.2)** process parameter ([GID-2670699](#)))
  - Example:  
Wait was aborted.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

- Wait for Event (OES) Phase (SR0540+)
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#### 9.4.1.2 GID-2670701 ABORT WAIT - LOGIC (SR0540.3.2.1.1)

- Trigger: Phase received abort message
- Postcondition: Exception is recorded

Step	#	Description
Abort message received	10	Phase automatically records exception without user interaction.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

## 9.5 Output Variables (SR0540.9+)

The following output variables are available to reference the phase's output.

### 9.5.1 *Instance count (Framework capability)*

- Data type: Long
- Usage: The output variable provides the count of the number of instances the phase has been processed, for example in a loop. The count is also increased when the phase is skipped from an operator's perspective, since the phase is still executed, but as a hidden phase.  
The count variable of a phase that has not been executed provides 0 as output value.

### 9.5.2 *Start time (Framework capability)*

- Data type: Timestamp
- Usage: The output variable provides the start time of the phase.

### 9.5.3 *Completion time (Framework capability)*

- Data type: Timestamp
- Usage: The output variable provides the completion time of the phase.

### 9.5.4 *Identifier (Framework capability)*

- Data type: String
- Usage: The output variable provides the identifier of the phase.

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### **9.5.5 *GID-2668805 Wait aborted (SR0540.9.1)***

- Data type: Boolean
- Values: true, false
- Usage: The output variable states if the wait state was aborted.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

## **9.6 Configuration Keys (SR0540.11+)**

The following configuration keys are available to configure the phase's behavior.

### **9.6.1 *GID-2668806 Message broker URL (SR0540.11.1)***

- Phase/DCS/DCSMesssageBrokerURL
- **Type:** String
- **Value:** tcp://<hostname>:<port>
- **Description:** Specifies the URL of the messaging server used for DCS communication. Replace <hostname> with the name of the host to be used and <port> with the port number of the host to be used.  
If no value is set, the URL defined in the PharmaSuite **MessageBrokerURL** configuration key is used.
- **Evaluated:** When a DCS phase communicates with a DCS.
- **Range:** N/A

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

- Wait for Event (OES) Phase (SR0540+)
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### **9.6.2 GID-2668807 Messaging timeout (SR0540.11.2)**

- Phase/DCS/DCSMessagingTimeout
- **Type:** Long
- Value: 2
- **Description:** The messaging timeout for DCS communication in seconds and the time how long a produced DCS message shall be retained by the messaging system after it has been dispatched.  
If no value is set, the timeout defined in the PharmaSuite **MessagingTimeout** configuration key is used (converted into seconds).
- **Evaluated:** When a DCS phase communicates with a DCS.
- **Range:** N/A

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

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## 10 Wait for Event Phase (SR0545+)

The **Wait for event** phase waits for an event from a DCS and allows to automatically synchronize an operation and the DCS or any other operator-run operation.

In case the **Send event (SR0550+)** phase ([GID-2667743](#)) or a DCS runs in the asynchronous mode, it is not necessary that the targeted **Wait for event** phase is already running.

Example use cases are:

- Receive a message from an automation system  
A process has reached a certain stage on the automation system and the MES can continue with this process.
- Remind the operator of a task  
After the operator has verified that a manufacturing step was completed, the operator must receive a reminder after a defined period of time to proceed with a further procedural step.  
This example makes use of the **Time-based trigger (SR0400+)** phase (see "Functional Requirement Specification IPC Phases" [A5] ([GID-2667776](#))).

The timestamp when the message was received, the message identifier, and the information whether the wait process was aborted or not is stored in the batch record, thereby becoming available for documentation purposes in the sub-report and batch report ([GID-2668796](#)).

Anomalies that occur during processing are covered by the phase exception handling ([GID-2667729](#)) (e.g. abort wait).

After completion the phase displays the message identifier and the phase's aborted state in the Execution Window.

The Navigator displays the timestamp when the message was received.

Wait for DCS completion.

Waiting for COMPLETED message.

Confirm



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*Figure 8: Wait for event during execution*

## 10.1 Layout

The phase provides individual layouts for its representation during execution ([\(GID-2668808\)](#), in the Navigator ([\(GID-2668809\)](#), and in the sub-report ([\(GID-2668810\)](#).

### 10.1.1 Representation during Execution (SR0545.1+)

The representation during execution depends on the phase mode.

#### 10.1.1.1 GID-2670702 PREVIEW MODE (SR0545.1.1)

1. <Instruction text>  
(taken from **Instruction (SR0545.8.3)** process parameter ([\(GID-2670714\)](#))
2. Message-specific information:
  - Waiting for <message identifier> message.  
Initial message.
3. **Confirm** button (disabled).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	Medium
MES-Compliance: 21 CFR Part 11 relevance	No

#### 10.1.1.2 GID-2670703 ACTIVE MODE (SR0545.1.2)

1. Instruction table panel and/or instruction link panel  
(only if an instruction table and/or instruction link is defined for the phase)
2. <Instruction text>  
(taken from **Instruction (SR0545.8.3)** process parameter ([\(GID-2670714\)](#))
3. Message-specific information:
  - Waiting for <message identifier> message.  
Initial message.
4. **Confirm** button.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

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#### 10.1.1.3 GID-2670704 COMPLETED MODE (SR0545.1.3)

1. Instruction table panel and/or instruction link panel  
(only if an instruction table and/or instruction link is defined for the phase)
2. <Instruction text>  
(taken from **Instruction (SR0545.8.3)** process parameter ([GID-2670714](#)))
3. Message-specific information:
  - <Message identifier> received.  
A message has been received.
  - Wait for <message identifier> aborted.  
Wait was aborted with the **Abort Wait (SR0545.3.1.1)** user-triggered exception ([GID-2670717](#)).
4. **Confirm** button (completed).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

#### 10.1.2 Representation in Navigator (SR0545.4+)

The Navigator provides the following details:

##### 10.1.2.1 PHASE COLUMN (FRAMEWORK CAPABILITY)

- <Phase name>
  - Example:  
Wait for cleaning

##### 10.1.2.2 GID-2670706 INFORMATION COLUMN (SR0545.4.1)

- <Message timestamp>
  - Example: 04/10/2018 11:59:46 AM CEST

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	Medium
MES-Compliance: 21 CFR Part 11 relevance	No

##### 10.1.2.3 ACTION COLUMN

- There are no phase-specific actions available.

#### 10.1.3 Representation in Sub-report (SR0545.5+)

The sub-report contains the following information:

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#### 10.1.3.1 COMMON SUB-REPORT ELEMENTS (FRAMEWORK CAPABILITY)

- <Start time>
- <Completion time>
- <Unit procedure> / <operation> / <phase>
- <Work center> / <station> / <device> - <phase completion user>

#### 10.1.3.2 GID-2670709 SUB-REPORT ELEMENTS (SR0545.5.1)

- Instruction table panel and/or instruction link panel  
(only if an instruction table and/or instruction link is defined for the phase)
- Instruction text
- Timestamp when the message was received
- Identifier of the received message
- Aborted: Yes/No

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

## 10.2 Business Logic (SR0545.2+)

The phase implements the following business logic.

#### 10.2.1 GID-2668811 Wait for event (SR0545.2.1)

- Function: Phase waits for event message
- Trigger: Phase becomes active
- Postcondition: Phase is completed

Step	#	Description
Phase activation	10	Phase waits for an event message with the identifier as defined with the <b>Event message (SR0545.8.1)</b> process parameter ( <a href="#">GID-2670715</a> ).
Phase receives message	20	Phase processes the received message. <ul style="list-style-type: none"> <li>▪ Request from the DCS to synchronize between the DCS and the order of the phase.</li> </ul> <p>OR</p> <ul style="list-style-type: none"> <li>▪ Request from the <b>Send event (SR0550+)</b> phase (<a href="#">GID-2667743</a>) to synchronize between the phases during processing of the order of the phases.</li> </ul>

- Wait for Event Phase (SR0545+)
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Step	#	Description
		<p>In case the <b>Send event (SR0550+)</b> phase (<a href="#">GID-2667743</a>) runs in the asynchronous mode and the timeout period of a sent event message has elapsed, there is no event message to be processed.</p> <p>OR</p> <ul style="list-style-type: none"> <li>Operator creates the <b>Abort Wait (SR0545.3.1.1)</b> user-triggered exception (<a href="#">GID-2670717</a>)</li> </ul>
Phase completion	30	Phase sets the <b>Wait aborted (SR0545.9.1)</b> output variable ( <a href="#">GID-2668823</a> ) Phase is completed.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

## 10.3 Process Parameters (SR0545.8+)

The following process parameters define the behavior of the phase.

### 10.3.1 Instruction Table-specific Parameters

#### 10.3.1.1 INSTRUCTION TABLE DEFINITION (FRAMEWORK CAPABILITY)

Attribute	Type	Comment
Table layout	Choice list	Defines the layout of the instruction table holding the instruction texts. Available settings: <b>1 column</b> , <b>2 columns</b> , <b>3 columns</b> , <b>4 columns</b> , <b>5 columns</b> . Default setting: <b>1 column</b> .
First column narrow	Boolean	Defines if the first column of the table shall be narrow.
Show all borders	Boolean	Defines if the borders of the table shall be visible.

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#### 10.3.1.2 INSTRUCTION TABLE TEXT (FRAMEWORK CAPABILITY)

Attribute	Type	Comment
Column 1	HTML text	Instruction text to be displayed in a column.
Column 2	HTML text	<b>Restriction:</b> Maximum length is 2000 characters (including HTML tags).
Column 3	HTML text	
Column 4	HTML text	
Column 5	HTML text	

#### 10.3.2 Instruction Link-specific Parameters

##### 10.3.2.1 INSTRUCTION TEXT WITH LINKS (FRAMEWORK CAPABILITY)

Attribute	Type	Comment
Instruction text	HTML text	<p>Instruction text to be displayed. For any text enclosed in curly brackets you can define a hyperlink with the <b>Instruction link definition</b> process parameter (<a href="#">GID-2670713</a>). Example: Refer to {SOP1270} for guidance.</p> <p>Maximum length is 2000 characters (including HTML tags).</p>

##### 10.3.2.2 INSTRUCTION LINK DEFINITION (FRAMEWORK CAPABILITY)

Attribute	Type	Comment
Link text	Text	<p>Text to be used as link. For any text enclosed in curly brackets within the instruction text you can define a link with the <b>Link URL</b> attribute. Including the brackets in the link text is optional.</p> <p>Maximum length is 80 characters.</p>

- Wait for Event Phase (SR0545+)
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Attribute	Type	Comment
Link URL	Text	URL of the file to be displayed. The link opens the external application assigned to the file type by the operating system. Maximum length is 256 characters.

### 10.3.3 Basic Parameters

#### 10.3.3.1 GID-2670714 INSTRUCTION (SR0545.8.3)

Attribute	Type	Comment
Text	HTML text	Instruction text to be displayed. <b>Restriction:</b> Maximum length is 4000 characters (including HTML tags).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

#### 10.3.3.2 GID-2670715 EVENT MESSAGE (SR0545.8.1)

Attribute	Type	Comment
Identifier	String	Identifier of the message to be received from the DCS or the <b>Send event (SR0550+)</b> phase ( <a href="#">GID-2667743</a> ). Maximum length is 80 characters.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

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#### **10.3.4 Configuration of User-triggered Exceptions**

##### **10.3.4.1 GID-2670716 ABORT WAIT (SR0545.8.2)**

Attribute	Type	Comment
Risk assessment	Choice list	Defines the risk level of the exception. Since there is no operator interaction for the exception, it is not linked to a signature privilege. Available settings: <b>None</b> , <b>Low</b> , <b>Low (mandatory comment)</b> , <b>Medium</b> , <b>Medium (mandatory comment)</b> , <b>High</b> , <b>High (mandatory comment)</b> . Default setting: <b>High</b> .
Exception text	Text	Defines the exception description used during exception handling and within the batch record. Maximum length is 250 characters.

See also Abort wait (SR0545.3.1.1) user-triggered exception [\(GID-2670717\)](#)

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

#### **10.4 Exceptions (SR0545.3+)**

The phase supports user-defined, user-triggered [\(GID-2668817\)](#), system-triggered link, and post-completion exceptions [\(GID-2789583\)](#) and their configuration by means of process parameters [\(GID-2667735\)](#).

User-defined exceptions cannot be configured by process parameters since they are provided by the framework and independent of phases.

##### **10.4.1 System-triggered Exceptions**

There are no system-triggered exceptions available.

##### **10.4.2 User-triggered Exceptions (SR0545.3.1+)**

A user-triggered exception is represented in the list of available user-triggered exceptions in the Exception Window, as the description of the exception, and in the batch report.

The following user-triggered exceptions are available.

- Wait for Event Phase (SR0545+)
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#### 10.4.2.1 GID-2670717 ABORT WAIT (SR0545.3.1.1)

The **Abort wait** exception allows an operator to abort the wait process.

Representation of the exception:

- Instruction:  
Abort the wait.  
**Confirm** button.
- Exception text:  
<Exception text>  
(taken from **Abort wait (SR0545.8.2)** process parameter ([GID-2670716](#)))  
▪ Example:  
Wait was aborted.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

#### 10.4.2.2 GID-2670718 ABORT WAIT - LOGIC (SR0545.3.1.1.1)

- Trigger: Exception is selected
- Postcondition: Exception is recorded

Step	#	Description
Operator confirms and signs exception	10	Phase records the exception.
	20	Phase sets the <b>Wait aborted (SR0545.9.1)</b> output variable ( <a href="#">GID-2670718</a> ) to <b>true</b> and completes automatically.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

#### 10.4.3 Post-completion Exceptions

There are no post-completion exceptions available.

### 10.5 Information Messages

There are no information messages available.

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## 10.6 Questions

There are no questions available.

## 10.7 Decisions

There are no decisions available.

## 10.8 Error Messages

There are no error messages available.

## 10.9 Output Variables (SR0545.9+)

The following output variables are available to reference the phase's output.

### 10.9.1 Instance count (*Framework capability*)

- Data type: Long
- Usage: The output variable provides the count of the number of instances the phase has been processed, for example in a loop. The count is also increased when the phase is skipped from an operator's perspective, since the phase is still executed, but as a hidden phase.  
The count variable of a phase that has not been executed provides 0 as output value.

### 10.9.2 Start time (*Framework capability*)

- Data type: Timestamp
- Usage: The output variable provides the start time of the phase.

### 10.9.3 Completion time (*Framework capability*)

- Data type: Timestamp
- Usage: The output variable provides the completion time of the phase.

### 10.9.4 Identifier (*Framework capability*)

- Data type: String
- Usage: The output variable provides the identifier of the phase.

### 10.9.5 GID-2668823 Wait aborted (SR0545.9.1)

- Data type: Boolean
- Values: true, false
- Usage: The output variable states if the wait state was aborted.

- Wait for Event Phase (SR0545+)
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Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

## 10.10 Configuration Keys (SR0545.11+)

The following configuration keys are available to configure the phase's behavior.

### 10.10.1 *GID-2668824 Message broker URL (SR0545.11.1)*

- Phase/DCS/DCSMessagingBrokerURL
- **Type:** String
- **Value:** tcp://<hostname>:<port>
- **Description:** Specifies the URL of the messaging server used for DCS communication. Replace <hostname> with the name of the host to be used and <port> with the port number of the host to be used.  
If no value is set, the URL defined in the PharmaSuite **MessageBrokerURL** configuration key is used.
- **Evaluated:** When a DCS phase communicates with a DCS.
- **Range:** N/A

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

### 10.10.2 *GID-2668825 Messaging timeout (SR0545.11.2)*

- Phase/DCS/DCSMessagingTimeout
- **Type:** Long
- **Value:** 2
- **Description:** The messaging timeout for DCS communication in seconds and the time how long a produced DCS message shall be retained by the messaging system after it has been dispatched.  
If no value is set, the timeout defined in the PharmaSuite **MessagingTimeout** configuration key is used (converted into seconds).
- **Evaluated:** When a DCS phase communicates with a DCS.
- **Range:** N/A

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

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## 11 Send Event Phase (SR0550+)

The **Send event** phase sends an event (PharmaSuite message) that is targeted at a **Wait for event (OES) (SR0540+)** phase ([GID-2667725](#)) or a **Wait for event (SR0545+)** phase ([GID-2667732](#)) to support the synchronization between an MES and a DCS or between operations of an order. In its asynchronous mode, it is not necessary that the targeted **Wait for event** phase is already running when the **Send event** phase sends its request.

Example use cases are:

- Send a message to synchronize manufacturing steps  
A process has reached a certain stage that allows another waiting manufacturing step to continue with its process.
- Remind the operator of a task  
After the operator verified that a manufacturing step was completed, the operator must receive a reminder after a defined period of time to proceed with a further procedural step.  
This example makes use of the **Time-based trigger (SR0400+)** phase (see "Functional Requirement Specification IPC Phases" [A5] ([GID-2667776](#))).

The timestamp when the message was sent, the message identifier, and the event type used by the message is stored in the batch record, thereby becoming available for documentation purposes in the sub-report and batch report ([GID-2668828](#)).

Anomalies that occur during processing are covered by the phase exception handling ([GID-2667747](#)) ([GID-2667747](#)) (e.g. sending failed).

The Navigator displays the message identifier and the event type of the message that was sent.

After completion the phase displays the message identifier and the timestamp when the message was sent.

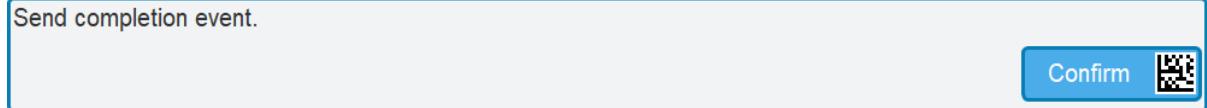


Figure 9: Send event during execution (normal event)

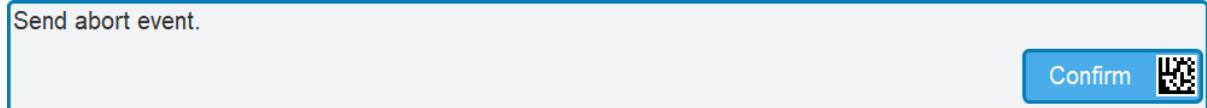


Figure 10: Send event during execution (normal event)

### 11.1 Layout

The phase provides individual layouts for its representation during execution ([GID-2432537](#)), in the Navigator ([GID-2432538](#)), and in the sub-report ([GID-2432541](#)).

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### **11.1.1 Representation during Execution (SR0550.1+)**

The representation during execution depends on the phase mode.

#### **11.1.1.1 GID-2670719 PREVIEW MODE (SR0550.1.1)**

1. <Instruction text>  
(taken from **Instruction (SR0550.8.1)** process parameter [\(GID-2670731\)](#))
2. **Confirm** button (disabled).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	Medium
MES-Compliance: 21 CFR Part 11 relevance	No

#### **11.1.1.2 GID-2670720 ACTIVE MODE (SR0550.1.2)**

1. Instruction table panel and/or instruction link panel  
(only if an instruction table and/or instruction link is defined for the phase)
2. <Instruction text>  
(taken from **Instruction (SR0550.8.1)** process parameter [\(GID-2670731\)](#))
3. **Confirm** button.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

#### **11.1.1.3 GID-2670721 COMPLETED MODE (SR0550.1.3)**

1. Instruction table panel and/or instruction link panel  
(only if an instruction table and/or instruction link is defined for the phase)
2. <Instruction text>  
(taken from **Instruction (SR0550.8.1)** process parameter [\(GID-2670731\)](#))
3. Message-specific information:
  - Message sent: <timestamp>
  - Abort message sent: <timestamp>
  - N/A is displayed as timestamp in case no message was sent.
4. **Confirm** button (completed).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

- Send Event Phase (SR0550+)

### **11.1.2 Representation in Navigator (SR0550.4+)**

The Navigator provides the following details:

#### **11.1.2.1 PHASE COLUMN (FRAMEWORK CAPABILITY)**

- <Phase name>
  - Example:  
Send message

#### **11.1.2.2 GID-2670723 INFORMATION COLUMN (SR0550.4.1)**

- <Event message / Event type>
- <Identifier> / Normal
- <Identifier> / Abort
- N/A (as identifier)

No message identifier was defined with the **Event message (SR0550.8.3)** process parameter.  
[\(GID-2670733\)](#)

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	Medium
MES-Compliance: 21 CFR Part 11 relevance	No

#### **11.1.2.3 ACTION COLUMN**

- There are no phase-specific actions available.

### **11.1.3 Representation in Sub-report (SR0550.5+)**

The sub-report contains the following information:

#### **11.1.3.1 COMMON SUB-REPORT ELEMENTS (FRAMEWORK CAPABILITY)**

- <Start time>
- <Completion time>
- <Unit procedure> / <operation> / <phase>
- <Work center> / <station> / <device> - <phase completion user>

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#### 11.1.3.2 GID-2670726 SUB-REPORT ELEMENTS (SR0550.5.1)

- Instruction table panel and/or instruction link panel  
(only if an instruction table and/or instruction link is defined for the phase)
- Instruction text
- Asynchronous mode:
- Yes/No
- Timeout period
- Timestamp when the message was sent  
N/A in case no message was sent
- Identifier of the message
- Aborted: Yes/No

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

#### 11.2 Business Logic (SR0550.2+)

The phase implements the following business logic.

##### 11.2.1 GID-2668829 Send event in manual completion mode (SR0550.2.1)

- Function: Phase sends message in manual completion mode of the phase
- Trigger: Phase becomes active
- Postcondition: Phase is completed

Step	#	Description
Phase activation	10	<p>Phase displays its user interface according to the <b>Active mode (SR0550.1.2)</b> layout (<a href="#">GID-2670720</a>).</p> <p>In case the phase is not configured as required, phase displays the <b>Configuration error (SR0550.3.6.1)</b> error message (<a href="#">GID-2668838</a>)</p>

- Send Event Phase (SR0550+)

Step	#	Description
Operator confirms phase	20	<p>Phase sends event message (only if the <b>Send abort event (SR0550.8.4)</b> process parameter (<a href="#">GID-2670734</a>) is set to <b>No</b>):</p> <ul style="list-style-type: none"> <li>▪ All <b>Wait for event (OES)</b> phases and <b>Wait for event</b> phases of the order can process the event message.</li> <li>▪ If the phase runs in the asynchronous mode (<b>Enabled</b> attribute of the <b>Send asynchronous message (SR0550.8.6)</b> process parameter (<a href="#">GID-2670735</a>) is set to <b>Yes</b>) and if the message has been sent successfully, continue with step 30 or if the message has not been sent successfully, phase creates the <b>Skip after failed sending (SR0550.3.2.1)</b> system-triggered exception (<a href="#">GID-2670737</a>)</li> <li>▪ If the phase does not run in the asynchronous mode (<b>Enabled</b> attribute of the <b>Send asynchronous message (SR0550.8.6)</b> process parameter (<a href="#">GID-2670735</a>) is set to <b>No</b>) and if the phase receives a reply before the timeout period has elapsed, continue with step 30 or if the phase does not receive a reply before the timeout period has elapsed, phase creates the <b>Skip after failed sending (SR0550.3.2.1)</b> system-triggered exception (<a href="#">GID-2670737</a>).</li> </ul> <p>Phase sends a broadcast (abort message) (only if the <b>Send abort event (SR0550.8.4)</b> process parameter (<a href="#">GID-2670734</a>) is set to <b>Yes</b>):</p> <ul style="list-style-type: none"> <li>▪ All <b>Wait for event (OES)</b> phases of the unit procedure can process the abort message. Continue with step 30.</li> </ul>
Phase completion	30	Phase is completed.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

### 11.2.2 **GID-2668830 Send event in automatic completion mode (SR0550.2.2)**

- Function: Phase sends message in automatic completion mode of the phase
- Trigger: Phase becomes active
- Postcondition: Phase is completed

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Step	#	Description
Phase activation	10	<p>In case the phase is not configured as required, phase displays the <b>Configuration error (SR0550.3.6.1)</b> error message (<a href="#">GID-2668838</a>).</p> <p>Phase sends event message (only if the <b>Send abort event (SR0550.8.4)</b> process parameter (<a href="#">GID-2670734</a>) is set to <b>No</b>):</p> <ul style="list-style-type: none"> <li>▪ All <b>Wait for event (OES)</b> phases and <b>Wait for event</b> phases of the order can process the event message.</li> <li>▪ If the phase runs in the asynchronous mode (<b>Enabled</b> attribute of the <b>Send asynchronous message (SR0550.8.6)</b> process parameter (<a href="#">GID-2670735</a>) is set to <b>Yes</b>) and if the message has been sent successfully, continue with step 20 or if the message has not been sent successfully, phase creates the <b>Skip after failed sending (SR0550.3.2.1)</b> system-triggered exception (<a href="#">GID-2670737</a>).</li> <li>▪ If the phase does not run in the asynchronous mode (<b>Enabled</b> attribute of the <b>Send asynchronous message (SR0550.8.6)</b> process parameter (<a href="#">GID-2670735</a>) is set to <b>No</b>) and if the phase receives a reply before the timeout period has elapsed, continue with step 20 or if the phase does not receive a reply before the timeout period has elapsed, phase creates the <b>Skip after failed sending (SR0550.3.2.1)</b> system-triggered exception (<a href="#">GID-2670737</a>). Phase must be completed manually. See <b>Send Event in Manual Completion Mode (SR0550.2.1)</b> mode (<a href="#">GID-2668829</a>).</li> </ul> <p>Phase sends a broadcast (abort message) (only if the <b>Send abort event (SR0550.8.4)</b> process parameter (<a href="#">GID-2670734</a>) is set to <b>Yes</b>):</p> <ul style="list-style-type: none"> <li>▪ All <b>Wait for event (OES)</b> phases of the unit procedure can process the abort message.</li> </ul>
Phase completion	20	Phase is completed.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

- Send Event Phase (SR0550+)
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## 11.3 Process Parameters (SR0550.8+)

The following process parameters define the behavior of the phase.

### 11.3.1 Instruction Table-specific Parameters

#### 11.3.1.1 INSTRUCTION TABLE DEFINITION (FRAMEWORK CAPABILITY)

Attribute	Type	Comment
Table layout	Choice list	Defines the layout of the instruction table holding the instruction texts. Available settings: <b>1 column</b> , <b>2 columns</b> , <b>3 columns</b> , <b>4 columns</b> , <b>5 columns</b> . Default setting: <b>1 column</b> .
First column narrow	Boolean	Defines if the first column of the table shall be narrow.
Show all borders	Boolean	Defines if the borders of the table shall be visible.

#### 11.3.1.2 INSTRUCTION TABLE TEXT (FRAMEWORK CAPABILITY)

Attribute	Type	Comment
Column 1	HTML text	Instruction text to be displayed in a column.
Column 2	HTML text	<b>Restriction:</b> Maximum length is 2000 characters (including HTML tags).
Column 3	HTML text	
Column 4	HTML text	
Column 5	HTML text	

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### **11.3.2 Instruction Link-specific Parameters**

#### **11.3.2.1 INSTRUCTION TEXT WITH LINKS (FRAMEWORK CAPABILITY)**

Attribute	Type	Comment
Instruction text	HTML text	<p>Instruction text to be displayed.</p> <p>For any text enclosed in curly brackets you can define a hyperlink with the <b>Instruction link definition</b> process parameter (<a href="#">GID-2670730</a>).</p> <p>Example: Refer to {SOP1270} for guidance.</p> <p>Maximum length is 2000 characters (including HTML tags).</p>

#### **11.3.2.2 INSTRUCTION LINK DEFINITION (FRAMEWORK CAPABILITY)**

Attribute	Type	Comment
Link text	Text	<p>Text to be used as link.</p> <p>For any text enclosed in curly brackets within the instruction text you can define a link with the <b>Link URL</b> attribute.</p> <p>Including the brackets in the link text is optional.</p> <p>Maximum length is 80 characters.</p>
Link URL	Text	<p>URL of the file to be displayed. The link opens the external application assigned to the file type by the operating system.</p> <p>Maximum length is 256 characters.</p>

- Send Event Phase (SR0550+)
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### 11.3.3 Basic Parameters

#### 11.3.3.1 GID-2670731 INSTRUCTION (SR0550.8.1)

Attribute	Type	Comment
Text	HTML text	Instruction text to be displayed. <b>Restriction:</b> Maximum length is 4000 characters (including HTML tags).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

#### 11.3.3.2 GID-2670732 MODE (SR0550.8.2)

Attribute	Type	Comment
Mode	Choice list	Defines the processing mode. <b>Manual completion</b> (default): Operator confirms the phase. <b>Automatic completion</b> : Phase is automatically completed after the reply to the sent event has been received or the broadcast (abort message) has been sent.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

#### 11.3.3.3 GID-2670733 EVENT MESSAGE (SR0550.8.3)

Attribute	Type	Comment
Identifier	String	Identifier of the message to be sent to a <b>Wait for event</b> phase. Maximum length is 80 characters.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

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#### 11.3.3.4 GID-2670734 SEND ABORT EVENT (SR0550.8.4)

Attribute	Type	Comment
Enabled	Boolean	Controls if the phase can send abort events. To abort a specific <b>Wait for event (OES)</b> phase, ensure that the corresponding message identifier is defined with the <b>Event message</b> process parameter. To abort all <b>Wait for event (OES)</b> phases of the unit procedure, ensure that no message identifier is defined with the <b>Event message</b> process parameter. Default setting: <b>No</b> .

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

#### 11.3.3.5 GID-2670735 SEND ASYNCHRONOUS MESSAGE (SR0550.8.6)

Attribute	Type	Comment
Enabled	Boolean	Controls if the phase runs in the asynchronous mode. If so, the phase does not wait for a reply message from a <b>Wait for event</b> phase in case the <b>Send abort event (SR0550.8.4)</b> process parameter ( <a href="#">GID-2670734</a> ) is set to <b>No</b> . A broadcast (abort message) is not considered in the asynchronous mode. Default setting: <b>No</b> .
Timeout period	Duration	Defines the time to live of the message in milliseconds.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

- Send Event Phase (SR0550+)
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#### 11.3.4 Configuration of System-triggered Exceptions

##### 11.3.4.1 GID-2670736 SKIP AFTER FAILED SENDING (SR0550.8.5)

Attribute	Type	Comment
Risk assessment	Choice list	Defines the risk level of the exception. Since there is no operator interaction for the exception, it is not linked to a signature privilege. Available settings: <b>None</b> , <b>Low</b> , <b>Low (mandatory comment)</b> , <b>Medium</b> , <b>Medium (mandatory comment)</b> , <b>High</b> , <b>High (mandatory comment)</b> . Default setting: <b>High</b> .
Exception text	Text	Defines the exception description used during exception handling and within the batch record. Maximum length is 250 characters.

See also [Skip after failed sending \(SR0550.3.2.1\)](#) system-triggered exception ([GID-2670737](#)).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

#### 11.4 Exceptions (SR0550.3+)

The phase supports user-defined, user-triggered ([GID-2668836](#)), system-triggered ([GID-2668835](#)), and post-completion exceptions ([GID-2668837](#)) and their configuration by means of process parameters ([GID-2667746](#)).

User-defined exceptions cannot be configured by process parameters since they are provided by the framework and independent of phases.

##### 11.4.1 System-triggered Exceptions (SR0550.3.2+)

A system-triggered exception is represented in a message dialog along with an **Exception** button, in the Exception Window as the read-only description of the exception, and in the batch report.

The following system-triggered exceptions are available.

##### 11.4.1.1 GID-2670737 SKIP AFTER FAILED SENDING (SR0550.3.2.1)

In case the event message that is targeted at a **Wait for event** phase cannot be sent successfully, the system automatically records a system-triggered exception.

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Representation of the exception:

- <Exception text>  
(taken from **Skip after failed sending (SR0550.8.5)** process parameter ([GID-2670736](#))  
Sending the message could not be completed. Cancel the exception to retry or sign the exception to abort the phase.
- Example:  
Message could not be sent.  
Sending the message could not be completed. Cancel the exception to retry or sign the exception to abort the phase.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

#### 11.4.1.2 GID-2670738 SKIP AFTER FAILED SENDING - LOGIC (SR0550.3.2.1.1)

- Trigger: Message(s) could not be sent
- Postcondition: Exception is recorded

Step	#	Description
Operator accepts exceptional situation	10.1	Phase shows exception description to be signed.
Operator signs exception	10.2	Phase records the exception and returns to the <b>Active mode (SR0550.1.2)</b> layout ( <a href="#">GID-2670720</a> ). (Operator can confirm the phase in order to complete the phase.)
Operator cancels exceptional situation in order to retry sending the event	20	Phase requests the operator to sign the cancelation of the exception and returns to the <b>Active mode (SR0550.3.2.1)</b> layout ( <a href="#">GID-2670737</a> ). (Operator can confirm the phase in order to retry sending the event and complete the phase.)

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

- Send Event Phase (SR0550+)
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#### **11.4.2 User-triggered Exceptions**

There are no user-triggered exceptions available.

#### **11.4.3 Post-completion Exceptions**

There are no post-completion exceptions available.

### **11.5 Information Messages**

There are no information messages available.

### **11.6 Questions**

There are no questions available.

### **11.7 Decisions**

There are no decisions available.

### **11.8 Error Messages (SR0550.3.6+)**

Error messages are represented in an error message dialog containing a message type-specific icon, the error message, and an **OK** button.

The following error messages are available to inform the operator about error conditions.

#### **11.8.1 GID-2668838 Configuration error (SR0550.3.6.1)**

UI text	Comment
Configuration error. There is no message identifier defined. Please repair or abort the phase.	Message pack: PhaseSendEvent<version> Message ID: noEventIdentifier_ErrorMsg

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

### **11.9 Output Variables (SR0550.9+)**

The following output variables are available to reference the phase's output.

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### **11.9.1 Instance count (*Framework capability*)**

- Data type: Long
- Usage: The output variable provides the count of the number of instances the phase has been processed, for example in a loop. The count is also increased when the phase is skipped from an operator's perspective, since the phase is still executed, but as a hidden phase.  
The count variable of a phase that has not been executed provides 0 as output value.

### **11.9.2 Start time (*Framework capability*)**

- Data type: Timestamp
- Usage: The output variable provides the start time of the phase.

### **11.9.3 Completion time (*Framework capability*)**

- Data type: Timestamp
- Usage: The output variable provides the completion time of the phase.

### **11.9.4 Identifier (*Framework capability*)**

- Data type: String
- Usage: The output variable provides the identifier of the phase.

## **11.10 Configuration Keys (SR0550.11+)**

The following configuration keys are available to configure the phase's behavior.

### **11.10.1 GID-2668843 Message broker URL (SR0550.11.1)**

- Phase/DCS/DCSMesssageBrokerURL
- **Type:** String
- **Value:** tcp://<hostname>:<port>
- **Description:** Specifies the URL of the messaging server used for DCS communication. Replace <hostname> with the name of the host to be used and <port> with the port number of the host to be used.  
If no value is set, the URL defined in the PharmaSuite **MessageBrokerURL** configuration key is used.
- **Evaluated:** When a DCS phase communicates with a DCS.
- **Range:** N/A

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

#### 11.10.2 *GID-2668844 Messaging timeout (SR0550.11.2)*

- Phase/DCS/DCSMessagingTimeout
- **Type:** Long
- Value: 2
- **Description:** The messaging timeout for DCS communication in seconds and the time how long a produced DCS message shall be retained by the messaging system after it has been dispatched.  
If no value is set, the timeout defined in the PharmaSuite **MessagingTimeout** configuration key is used (converted into seconds).
- **Evaluated:** When a DCS phase communicates with a DCS.
- **Range:** N/A

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

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## 12 Get DCS Parameters Phase (SR0526+)

The **Get DCS parameters** phase allows an operator to retrieve automation system parameter values through message queues.

Example use cases are:

- Document batch relevant parameters in the batch report that were used by the automated system and not set by the MES.
- Evaluate, document, and generate exceptions for batch-relevant parameters that are not within the limits defined by further automation parameters.

Different phase modes enable the usage in various situations that can occur during processing:

- In the **Manual completion** mode, the operator manually triggers retrieving the parameters.
- In the **Automatic completion** mode, the phase retrieves the parameters and is completed automatically without any operator interaction.

The DCS, batch, the batch parameters, and their values are stored in the batch record, thereby becoming available for documentation purposes in the sub-report and batch report (GID-2432927).

Anomalies that occur during processing are covered by the phase exception handling (GID-2432976) (e.g. limit violation).

After completion the phase displays the affected parameters and their values in the Execution Window.

The Navigator displays the identifier of the batch whose values were retrieved.

Collect the data from the DCS.

DCS name:	JavaDCSMock	Batch ID:	BX57_V399		
Unit ID:	U207-22	Product ID:	D130-01		
Recipe ID:	ID_SRTD-100	Data source:	Source 2		
Module IDs:					
Timestamp of last Get action: 03/24/2023 04:42:17 PM IST			Get		
Parameter	Parameter description	Expected	Limits ( LL   L )	Value	Limits ( H   HH )
Tablet Dimensions	Tablet dimensions value		8.8   8.9	9.0	9.1   9.2
Tablet Form	Tablet form (round)	Yes		Yes	
Status	Process status	OK		OK	
Order Start	Date and time of order start		11/23/2018 10:30:00 AM IST   11/24/2018 10:30:00 AM IST	11/26/2018 10:43:30 PM IST	11/28/2018 10:30:00 AM IST   11/29/2018 10:30:00 AM IST
Order Duration	Run duration of the order		3h   4h	7h	11h   12h

**Confirm**

Figure 11: Get DCS parameters during execution

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## 12.1 Layout

The phase provides individual layouts for its representation during execution ([GID-2668845](#)), in the Navigator ([GID-2668846](#)), and in the sub-report ([GID-2668847](#)).

### 12.1.1 Representation during Execution (SR0526.1+)

The representation during execution depends on the phase mode.

#### 12.1.1.1 GID-2670739 PREVIEW MODE (SR0526.1.1)

1. <Instruction text>  
(taken from **Instruction (SR0526.8.1)** process parameter ([GID-2670755](#)))
2. DCS name: <logical name>  
Batch ID: <identifier>  
Unit ID: <identifier>  
Recipe ID: <identifier>  
Product ID: <identifier>  
Data source: <value>  
Module IDs: <identifiers>  
(taken from **DCS (SR0526.8.2)** process parameter ([GID-2670757](#)) and **Definition (SR0526.8.3)** process parameter ([GID-2670758](#)))
3. **Get** button (disabled).
4. Get action-specific information:
  - Get action not performed yet.
5. List of up to 50 bundle parameters in the order of the bundle-specific process parameters:
  - **Boolean Value Bundle:**
    - Parameter  
Parameter description  
(taken from the boolean value-specific **Master bundle identifier (SR0526.8.6)** process parameter ([GID-2670761](#)))
    - Expected  
(taken from the boolean value-specific **Expected value definition (SR0526.8.8)** process parameter ([GID-2670766](#)))
    - Value

- **Boolean Value (Extended) Bundle:**

- Parameter  
(taken from the boolean value-specific **Master bundle identifier (SR0526.8.11)** process parameter ([GID-2670768](#)))
- Parameter description  
Expected  
Value

- **Duration Value Bundle:**

- Parameter  
Parameter description  
(taken from the duration value-specific **Master bundle identifier (SR0526.8.16)** process parameter ([GID-2670773](#)))
- Limits (LL | L)  
Limits (H | HH)  
(taken from the duration value-specific **Limit definition (SR0526.8.19)** process parameter ([GID-2670779](#)))
- Value

- **Duration Value (Extended) Bundle:**

- Parameter  
(taken from the duration value-specific **Master bundle identifier (SR0526.8.22)** process parameter ([GID-2670781](#)))
- Parameter description  
Limits (LL | L)  
Limits (H | HH)  
Value

- **Numeric Value Bundle:**

- Parameter  
Parameter description  
(taken from the numeric value-specific **Master (bundle identifier) (SR0526.8.28)** process parameter ([GID-2670789](#)))
- Limits (LL | L)  
Limits (H | HH)  
(taken from the numeric value-specific **Limit definition (SR0526.8.31)** process parameter ([GID-2670795](#)))
- Value

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- **Numeric Value (Extended) Bundle:**

- Parameter  
(taken from the numeric value-specific **Master (bundle identifier) (SR0526.8.34)** process parameter ([GID-2670797](#)))

- Parameter description  
Limits (LL | L)  
Limits (H | HH)  
Value

- **String Value Bundle:**

- Parameter  
Parameter description  
(taken from the string value-specific **Master bundle identifier (SR0526.8.40)** process parameter ([GID-2670805](#)))

- Expected  
(taken from the string value-specific **Expected value definition (SR0526.8.42)** process parameter ([GID-2670810](#)))

- Value

- **String (Extended) Value Bundle:**

- Parameter  
(taken from the string value-specific **Master bundle identifier (SR0526.8.45)** process parameter ([GID-2670811](#)))

- Parameter description  
Expected  
Value

- **Timestamp Value Bundle:**

- Parameter  
Parameter description  
(taken from the timestamp value-specific **Master bundle identifier (SR0526.8.50)** process parameter ([GID-2670818](#)))

- Limits (LL | L)  
Limits (H | HH)  
(taken from the timestamp value-specific **Limit definition (SR0526.8.53)** process parameter ([GID-2670824](#)))

- Value

- **Timestamp (Extended) Value Bundle:**
    - Parameter  
(taken from the timestamp value-specific **Master bundle identifier (SR0526.8.56)** process parameter ([GID-2670826](#)))
    - Parameter description  
Limits (LL | L)  
Limits (H | HH)  
Value
6. **Confirm** button (disabled).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	Medium
MES-Compliance: 21 CFR Part 11 relevance	No

#### 12.1.1.2 GID-2670740 ACTIVE MODE (SR0526.1.2)

1. Instruction table panel and/or instruction link panel  
(only if an instruction table and/or instruction link is defined for the phase)
2. <Instruction text>  
(taken from **Instruction (SR0526.8.1)** process parameter ([GID-2670755](#)))
3. DCS name: <logical name>  
Batch ID: <identifier>  
Unit ID: <identifier>  
Recipe ID: <identifier>  
Product ID: <identifier>  
Data source: <value>  
Module IDs: <identifiers>  
(taken from **DCS (SR0526.8.2)** process parameter ([GID-2670757](#)) and **Definition (SR0526.8.3)** process parameter ([GID-2670758](#)))
4. **Get** button.
5. Get action-specific information:
  - Get action not performed yet.  
Initial message.
  - Timestamp of last Get action: <timestamp>
6. List of up to 50 bundle parameters in the order of the bundle-specific process parameters:
  - **Boolean Value Bundle:**
    - Parameter  
Parameter description  
(taken from the boolean value-specific **Master bundle identifier (SR0526.8.6)** process parameter ([GID-2670761](#)))

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- Expected  
(taken from the boolean value-specific **Expected value definition (SR0526.8.8)** process parameter ([GID-2670766](#)))
- Value  
For the representation of the value, see **Get parameter values (SR0526.2.3)** function ([GID-2670749](#)).
- **Boolean Value (Extended) Bundle:**
- Parameter  
(taken from the boolean value-specific **Master bundle identifier (SR0526.8.11)** process parameter ([GID-2670768](#)))
  - Parameter description  
Expected  
Value  
For the representation of the value, see **Get parameter values (SR0526.2.3)** function ([GID-2670749](#)).
- **Duration Value Bundle:**
- Parameter  
Parameter description  
(taken from the duration value-specific **Master bundle identifier (SR0526.8.16)** process parameter ([GID-2670773](#)))
  - Limits (LL | L)  
Limits (H | HH)  
(taken from the duration value-specific **Limit definition (SR0526.8.19)** process parameter ([GID-2670779](#)))
  - Value  
For the representation of the value, see **Get parameter values (SR0526.2.3)** function ([GID-2670749](#)).
- **Duration Value (Extended) Bundle:**
- Parameter  
(taken from the duration value-specific **Master bundle identifier (SR0526.8.22)** process parameter ([GID-2670781](#)))
  - Parameter description  
Limits (LL | L)  
Limits (H | HH)  
Value  
For the representation of the value, see **Get parameter values (SR0526.2.3)** function ([GID-2670749](#)).

- **Numeric Value Bundle:**

- Parameter

Parameter description

(taken from the numeric value-specific **Master (bundle identifier) (SR0526.8.28)** process parameter ([GID-2670789](#)))

- Limits (LL | L)

Limits (H | HH)

(taken from the numeric value-specific **Limit definition (SR0526.8.31)** process parameter ([GID-2670795](#)))

- Value

For the representation of the value, see **Get parameter values (SR0526.2.3)** function ([GID-2670749](#)).

- **Numeric Value (Extended) Bundle:**

- Parameter

(taken from the numeric value-specific **Master (bundle identifier) (SR0526.8.34)** process parameter ([GID-2670797](#)))

- Parameter description

Limits (LL | L)

Limits (H | HH)

Value

For the representation of the value, see **Get parameter values (SR0526.2.3)** function ([GID-2670749](#)).

- **String Value Bundle:**

- Parameter

Parameter description

(taken from the string value-specific **Master bundle identifier (SR0526.8.40)** process parameter ([GID-2670805](#)))

- Expected

(taken from the string value-specific **Expected value definition (SR0526.8.42)** process parameter ([GID-2670810](#)))

- Value

For the representation of the value, see **Get parameter values (SR0526.2.3)** function ([GID-2670749](#)).

- **String Value (Extended) Bundle:**

- Parameter

(taken from the string value-specific **Master bundle identifier (SR0526.8.45)** process parameter ([GID-2670811](#)))

- Parameter description

Expected

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#### Value

For the representation of the value, see **Get parameter values (SR0526.2.3)** function ([GID-2670749](#))

- **Timestamp Value Bundle:**

- Parameter

Parameter description

(taken from the timestamp value-specific **Master bundle identifier (SR0526.8.50)** process parameter ([GID-2670818](#)))

- Limits (LL | L)

Limits (H | HH)

(taken from the timestamp value-specific **Limit definition (SR0526.8.53)** process parameter ([GID-2670824](#)))

- Value

For the representation of the value, see **Get parameter values (SR0526.2.3)** function ([GID-2670749](#)).

- **Timestamp Value (Extend) Bundle:**

- Parameter

(taken from the timestamp value-specific **Master bundle identifier (SR0526.8.56)** process parameter ([GID-2670826](#)))

- Parameter description

Limits (LL | L)

Limits (H | HH)

Value

For the representation of the value, see **Get parameter values (SR0526.2.3)** function ([GID-2670749](#)).

7. In case the values were sent by the DCS:

Dynamic parameter list with header row, up to 50 data rows, and 5 columns. Header and data are defined by the DCS.

8. **Confirm** button.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

#### 12.1.1.3 GID-2670741 COMPLETED MODE (SR0526.1.3)

1. Instruction table panel and/or instruction link panel  
(only if an instruction table and/or instruction link is defined for the phase)
2. <Instruction text>  
(taken from **Instruction (SR0526.8.1)** process parameter ([GID-2670755](#)))
3. DCS name: <logical name>  
Batch ID: <identifier>  
Unit ID: <identifier>  
Recipe ID: <identifier>  
Product ID: <identifier>  
Data source: <value>  
Module IDs: <identifiers>  
(taken from **DCS (SR0526.8.2)** process parameter ([GID-2670757](#)) and **Definition (SR0526.8.3)** process parameter ([GID-2670758](#)))
4. **Get** button.
5. Get action-specific information:
  - Timestamp of last Get action: <timestamp>
6. List of up to 50 bundle parameters in the order of the bundle-specific process parameters:
  - **Boolean Value Bundle:**
    - Parameter  
Parameter description  
(taken from the boolean value-specific **Master bundle identifier (SR0526.8.6)** process parameter ([GID-2670761](#)))
    - Expected  
(taken from the boolean value-specific **Expected value definition (SR0526.8.8)** process parameter ([GID-2670766](#)))
    - Value
  - **Boolean Value (Extended) Bundle:**
    - Parameter  
(taken from the boolean value-specific **Master bundle identifier (SR0526.8.11)** process parameter ([GID-2670768](#)))
    - Parameter description  
Expected  
Value  
For the representation of the value, see **Get parameter values (SR0526.2.3)** function ([GID-2670749](#)).

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▪ **Duration Value Bundle:**

- Parameter  
Parameter description  
(taken from the duration value-specific **Master bundle identifier (SR0526.8.16)** process parameter ([GID-2670773](#)))
- Limits (LL | L)  
Limits (H | HH)  
(taken from the duration value-specific **Limit definition (SR0526.8.19)** process parameter ([GID-2670779](#)))
- Value  
For the representation of the value, see **Get parameter values (SR0526.2.3)** function ([GID-2670749](#)).

▪ **Duration Value (Extended) Bundle:**

- Parameter  
(taken from the duration value-specific **Master bundle identifier (SR0526.8.22)** process parameter ([GID-2670781](#)))
- Parameter description  
Limits (LL | L)  
Limits (H | HH)  
Value  
For the representation of the value, see **Get parameter values (SR0526.2.3)** function ([GID-2670749](#)).

▪ **Numeric Value Bundle:**

- Parameter  
Parameter description  
(taken from the numeric value-specific **Master (bundle identifier) (SR0526.8.28)** process parameter ([GID-2670789](#)))
- Limits (LL | L)  
Limits (H | HH)  
(taken from the numeric value-specific **Limit definition (SR0526.8.31)** process parameter ([GID-2670795](#)))
- Value  
For the representation of the value, see **Get parameter values (SR0526.2.3)** function ([GID-2670749](#)).

- **Numeric Value (Extended) Bundle:**

- Parameter  
(taken from the numeric value-specific **Master (bundle identifier) (SR0526.8.34)** process parameter ([GID-2670797](#)))
- Parameter description  
Limits (LL | L)  
Limits (H | HH)  
Value  
For the representation of the value, see **Get parameter values (SR0526.2.3)** function ([GID-2670749](#)).

- **String Value Bundle:**

- Parameter  
Parameter description  
(taken from the string value-specific **Master bundle identifier (SR0526.8.40)** process parameter ([GID-2670805](#)))
- Expected  
(taken from the string value-specific **Expected value definition (SR0526.8.42)** process parameter ([GID-2670810](#)))
- Value

- **String Value (Extended) Bundle:**

- Parameter  
(taken from the string value-specific **Master bundle identifier (SR0526.8.45)** process parameter ([GID-2670811](#)))
- Parameter description  
Expected  
Value  
For the representation of the value, see **Get parameter values (SR0526.2.3)** function ([GID-2670749](#))

- **Timestamp Value Bundle:**

- Parameter  
Parameter description  
(taken from the timestamp value-specific **Master bundle identifier (SR0526.8.50)** process parameter ([GID-2670818](#)))
- Limits (LL | L)  
Limits (H | HH)  
(taken from the timestamp value-specific **Limit definition (SR0526.8.53)** process parameter ([GID-2670824](#)))
- Value

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▪ **Timestamp Value (Extend) Bundle:**

- Parameter  
(taken from the timestamp value-specific **Master bundle identifier (SR0526.8.56)** process parameter ([GID-2670826](#)))
- Parameter description  
Limits (LL | L)  
Limits (H | HH)  
Value  
For the representation of the value, see **Get parameter values (SR0526.2.3)** function ([GID-2670749](#)).

7. In case the values were sent by the DCS:

Dynamic parameter list with header row, up to 50 data rows, and 5 columns. Header and data are defined by the DCS.

8. **Confirm** button.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

### 12.1.2 Representation in Navigator (SR0526.4+)

The Navigator provides the following details:

#### 12.1.2.1 GID-2670742 INFORMATION COLUMN (SR0526.4.1)

- <Batch identifier>
  - Example: BX2859\_V15900

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	Medium
MES-Compliance: 21 CFR Part 11 relevance	No

#### 12.1.2.2 PHASE COLUMN (FRAMEWORK CAPABILITY)

- <Phase name>
  - Example:  
Retrieve values from DCS

#### 12.1.2.3 ACTION COLUMN

- There are no phase-specific actions available.

### **12.1.3 Representation in Sub-report (SR0526.5+)**

The sub-report contains the following information:

#### **12.1.3.1 COMMON SUB-REPORT ELEMENTS (FRAMEWORK CAPABILITY)**

- <Start time>
- <Completion time>
- <Unit procedure> / <operation> / <phase>
- <Work center> / <station> / <device> - <phase completion user>

#### **12.1.3.2 GID-2670746 SUB-REPORT ELEMENTS (SR0526.5.1)**

- Instruction table panel and/or instruction link panel  
(only if an instruction table and/or instruction link is defined for the phase)
- Instruction text
- DCS name: <logical name>  
Batch ID: <identifier>  
Unit ID: <identifier>  
Recipe ID: <identifier>  
Product ID: <identifier>  
Data source: <value>  
Module IDs: <identifiers>
- Get action-specific information:
- Timestamp: <timestamp>
- Table of values (boolean, boolean (extended), duration, duration (extended), numeric, numeric (extended), string, string (extended), timestamp, timestamp (extended) that have been retrieved during execution (in the order of the process parameters).
  - Parameter
  - Parameter description
  - Expected value
  - Limits (LL | L)
  - Value
  - Limits (H | HH)
  - In case the values were sent by the DCS:  
Dynamic parameter list with header row, up to 50 data rows, and 5 columns. Header and data are defined by the DCS.

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Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

## 12.2 Business Logic (SR0526.2+)

The phase implements the following business logic.

### 12.2.1 Phase Mode

Business logic related to phase modes.

#### 12.2.1.1 GID-2670747 MANUAL COMPLETION MODE (SR0526.2.1)

- Function: **Manual completion** mode of phase
- Type: Phase mode
- Trigger: Phase becomes active
- Postcondition: Phase is active

Step	#	Description
Phase activation	10	Phase displays its user interface according to the <b>Active mode (SR0526.1.2)</b> layout ( <a href="#">GID-2670740</a> ). In case the <b>Expected value/limits visible</b> in PEC process parameter is set to <b>No</b> , the phase displays empty cells with a blue background.
Operator taps <b>Get</b> button	20	The phase reads the parameter values from the DCS, see <b>Get parameter values (SR0526.2.3)</b> function ( <a href="#">GID-2670749</a> ). Each time the <b>Get</b> button is used, all of the parameter values are read unless they have already been read or overridden.
Phase completion	30	See <b>Confirm phase (SR0526.2.4)</b> function ( <a href="#">GID-2670750</a> ).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

#### 12.2.1.2 GID-2670748 AUTOMATIC COMPLETION MODE (SR0526.2.2)

- Function: **Automatic completion** mode of phase
- Type: Phase mode
- Trigger: Phase becomes active
- Postcondition: Phase is active

- Get DCS Parameters Phase (SR0526+)

Step	#	Description
Phase activation	10	<p>Phase displays its user interface according to the <b>Active mode (SR0526.1.2)</b> layout (<a href="#">GID-2670740</a>).</p> <p>In case the <b>Expected value/limits visible in PEC process parameter</b> is set to <b>No</b>, the phase displays empty cells with a blue background.</p>
Phase gets values	20	<p>See <b>Get parameter values (SR0526.2.3)</b> function (<a href="#">GID-2670749</a>).</p> <ul style="list-style-type: none"> <li>▪ If no error has occurred, continue with the <b>Confirm phase (SR0526.2.4)</b> function (<a href="#">GID-2670750</a>).</li> <li>▪ If an error or warning has occurred, phase must be completed manually. See <b>Manual completion (SR0526.2.1)</b> mode (<a href="#">GID-2670747</a>).</li> </ul>

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

### 12.2.2 Main Path

Business logic related to the main path:

#### 12.2.2.1 GID-2670749 GET PARAMETER VALUES (SR0526.2.3)

- Function: Retrieve parameters
- Type: Main path
- Trigger: Operator retrieves parameters or **Automatic completion (SR0526.2.2)** mode ([GID-2670748](#)) is active
- Postcondition: Phase is active

Step	#	Description
Phase checks manual override	10	If a value has been overridden with the <b>Override DCS parameter value (SR0526.3.1.1)</b> user-triggered exception ( <a href="#">GID-2670836</a> ) and the exception has been signed, the <b>Get</b> action cannot be executed for such a value; phase displays <b>Override value recorded (SR0526.3.4.1)</b> information message ( <a href="#">GID-2668867</a> ).
Phase checks for read parameter values of a bundle	15	If all parameter values of a bundle have already been read from the DCS, the <b>Get</b> action is not executed for the value of the bundle.

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Step	#	Description
Phase gets values	20	<p>Phase reads the remaining parameter bundles and disables the <b>Get</b> button as soon as there are no parameter bundles that have not yet been read or overridden.</p> <p>The order of the <b>Boolean value - Master (bundle identifier)</b> (SR0526.8.6) process parameters (<a href="#">GID-2670761</a>), <b>Boolean value (extended) - Master (bundle identifier)</b> (SR0526.8.11) process parameters (<a href="#">GID-2670768</a>), <b>Duration value - Master (bundle identifier)</b> (SR0526.8.16) process parameters (<a href="#">GID-2670773</a>), <b>Duration value (extended) - Master (bundle identifier)</b> (SR0526.8.22) process parameters (<a href="#">GID-2670781</a>), <b>Numeric value - Master (bundle identifier)</b> (SR0526.8.28) process parameters (<a href="#">GID-2670789</a>), <b>Numeric value (extended) - Master (bundle identifier)</b> (SR0526.8.34) process parameters (<a href="#">GID-2670797</a>), <b>String value - Master (bundle identifier)</b> (SR0526.8.40) process parameters (<a href="#">GID-2670805</a>), <b>String value (extended) - Master (bundle identifier)</b> (SR0526.8.45) process parameters (<a href="#">GID-2670811</a>), <b>Timestamp value - Master (bundle identifier)</b> (SR0526.8.50) process parameters (<a href="#">GID-2670818</a>), and <b>Timestamp value (extended) - Master (bundle identifier)</b> (SR0526.8.56) process parameters (<a href="#">GID-2670826</a>) defines the read sequence of the parameter values.</p> <p>If any issue occurs, phase behavior is as follows:</p> <ul style="list-style-type: none"> <li>▪ Phase does not display a value,</li> <li>▪ changes cell background to red,</li> <li>▪ appends "(X)" to the "empty value", and</li> <li>▪ displays <b>No get result error</b> (SR0526.3.6.1) error message (<a href="#">GID-2670838</a>).</li> </ul>
Validation	20.1	<ul style="list-style-type: none"> <li>▪ <b>Boolean Value Bundle</b> Phase checks the boolean value against the settings of the <b>Expected value definition</b> (SR0526.8.8) process parameter (<a href="#">GID-2670766</a>). If the check is violated, phase creates the <b>Limit violation</b> (SR0526.3.2.1) system-triggered exception (<a href="#">GID-2670833</a>) for a boolean value.</li> <li>▪ <b>Boolean Value (Extended) Bundle</b> Phase checks the boolean value against the value retrieved due to settings of the <b>Expected value definition parameter</b> (SR0526.8.13) process parameter (<a href="#">GID-2671666</a>). If the check is violated, phase creates the <b>Limit violation</b> (SR0526.3.2.1) system-triggered exception (<a href="#">GID-2670833</a>) for a boolean value (extended).</li> </ul>

Step	#	Description
		<ul style="list-style-type: none"> <li>▪ <b>Duration Value Bundle</b> Phase checks the duration value against the settings of the <b>Limit definition (SR0526.8.19)</b> process parameter (<a href="#">GID-2670779</a>). Limits are checked in the following order: LL/HH » L/H. If the check is violated, phase creates the <b>Limit violation (SR0526.3.2.1)</b> system-triggered exception (<a href="#">GID-2670833</a>) for a duration value.</li> <li>▪ <b>Duration Value (Extended) Bundle</b> Phase checks the duration value against the values retrieved due to settings of the <b>Limit definition parameters (SR0526.8.25)</b> process parameter (<a href="#">GID-2670787</a>). Limits are checked in the following order: LL/HH » L/H. If the check is violated, phase creates the <b>Limit violation (SR0526.3.2.1)</b> system-triggered exception (<a href="#">GID-2670833</a>) for a duration value (extended).</li> <li>▪ <b>Numeric Value Bundle</b> Phase checks the numeric value against the settings of the <b>Limit definition (SR0526.8.31)</b> process parameter (<a href="#">GID-2670795</a>). Limits are checked in the following order: LL/HH » L/H. If the check is violated, phase creates the <b>Limit violation (SR0526.3.2.1)</b> system-triggered exception (<a href="#">GID-2670833</a>) for a numeric value.</li> <li>▪ <b>Numeric Value (Extended) Bundle</b> Phase checks the numeric value against the values retrieved due to settings of the <b>Limit definition parameters (SR0526.8.37)</b> process parameter (<a href="#">GID-2670803</a>). Limits are checked in the following order: LL/HH » L/H. If the check is violated, phase creates the <b>Limit violation (SR0526.3.2.1)</b> system-triggered exception (<a href="#">GID-2670833</a>) for a numeric value (extended).</li> <li>▪ <b>String Value Bundle</b> Phase checks the string value against the settings of the <b>Expected value definition (SR0526.8.42)</b> process parameter (<a href="#">GID-2670810</a>). If the check is violated, phase creates the <b>Limit violation (SR0526.3.2.1)</b> system-triggered exception (GID-2430728) for a string value.</li> <li>▪ <b>String Value (Extended) Bundle</b> Phase checks the string value against the retrieved due to settings of the <b>Expected value definition parameter (SR0526.8.47)</b> process parameter (GID-2495755). If the check is violated, phase creates the <b>Limit violation (SR0526.3.2.1)</b> system-triggered exception (<a href="#">GID-2670833</a>) for a string value.</li> </ul>

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Step	#	Description
		<ul style="list-style-type: none"> <li>▪ <b>Timestamp Value Bundle</b> Phase checks the timestamp value against the settings of the <b>Limit definition (SR0526.8.53)</b> process parameter (<a href="#">GID-2670824</a>). Limits are checked in the following order: LL/HH » L/H. If the check is violated, phase creates the <b>Limit violation (SR0526.3.2.1)</b> system-triggered exception (<a href="#">GID-2670833</a>) for a timestamp value.</li> <li>▪ <b>Timestamp Value (Extended) Bundle</b> Phase checks the timestamp value against the values retrieved due to settings of the <b>Limit definition parameters (SR0526.8.59)</b> process parameter (<a href="#">GID-2670832</a>). Limits are checked in the following order: LL/HH » L/H. If the check is violated, phase creates the <b>Limit violation (SR0526.3.2.1)</b> system-triggered exception (<a href="#">GID-2670833</a>) for a timestamp value (extended).</li> <li>▪ If a check is violated, phase changes cell background to yellow. After the exception has been signed, phase changes cell background to the default and adds the exception marker to the value's cell.</li> <li>▪ If no check is violated, phase returns to the <b>Active mode (SR0526.1.2)</b> layout (<a href="#">GID-2670740</a>).</li> </ul>
	25	Phase checks if the dynamic table data was received from the DCS. If so, phase displays the values.
	30	<p>If applicable, continue with the <b>Override DCS parameter value (SR0526.3.1.1)</b> user-triggered exception (<a href="#">GID-2670836</a>).</p> <p>Phase can be completed with the <b>Confirm phase (SR0526.2.4)</b> function (<a href="#">GID-2670750</a>)</p>

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

#### 12.2.2.2 GID-2670750 CONFIRM PHASE (SR0526.2.4)

- Function: Completion of phase
- Type: Main path
- Trigger: Operator confirms phase or **Automatic completion (SR0526.2.2)** mode ([GID-2670748](#)) is active
- Postcondition: Phase is completed

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Step	#	Description
In Manual completion (SR0526.2.1) mode ( <a href="#">GID-2670747</a> ) Operator confirms phase	10	Operator confirms the parameter values.
Phase performs completion checks	20	<p>If one of the following issues occurs, phase cannot be completed:</p> <ul style="list-style-type: none"> <li>▪ In Manual completion (SR0526.2.1) mode (<a href="#">GID-2670747</a>), the Get button has not been used.</li> <li>▪ Not all parameter values that were defined have been overridden with the Override DCS parameter value (SR0526.3.1.1) user-triggered exception (<a href="#">GID-2670836</a>) or have been read.</li> </ul> <p>Phase displays Recorded values incomplete (SR0526.3.6.2) error message (<a href="#">GID-2670839</a>).</p> <p>If a validation check fails, phase creates the Limit violation (SR0526.3.2.1) system-triggered exception (<a href="#">GID-2670833</a>).</p> <p>Continue with the Override DCS parameter value (SR0526.3.1.1) user-triggered exception (<a href="#">GID-2670836</a>).</p>
Phase completion	30	Phase is completed.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

## 12.3 Process Parameters (SR0526.8+)

The following process parameters define the behavior of the phase.

### 12.3.1 Instruction Table-specific Parameters

#### 12.3.1.1 INSTRUCTION TABLE DEFINITION (FRAMEWORK CAPABILITY)

Attribute	Type	Comment
Table layout	Choice list	<p>Defines the layout of the instruction table holding the instruction texts.</p> <p>Available settings: 1 column, 2 columns, 3 columns, 4 columns, 5 columns.</p> <p>Default setting: 1 column.</p>

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Attribute	Type	Comment
First column narrow	Boolean	Defines if the first column of the table shall be narrow.
Show all borders	Boolean	Defines if the borders of the table shall be visible.

#### 12.3.1.2 INSTRUCTION TABLE TEXT (FRAMEWORK CAPABILITY)

Attribute	Type	Comment
Column 1	HTML text	Instruction text to be displayed in a column.
Column 2	HTML text	<b>Restriction:</b> Maximum length is 2000 characters (including HTML tags).
Column 3	HTML text	
Column 4	HTML text	
Column 5	HTML text	

#### 12.3.2 Instruction Link-specific Parameters

##### 12.3.2.1 INSTRUCTION TEXT WITH LINKS (FRAMEWORK CAPABILITY)

Attribute	Type	Comment
Instruction text	HTML text	<p>Instruction text to be displayed. For any text enclosed in curly brackets you can define a hyperlink with the <b>Instruction link definition</b> process parameter (<a href="#">GID-2670754</a>)</p> <p>Example: Refer to {SOP1270} for guidance.</p> <p>Maximum length is 2000 characters (including HTML tags).</p>

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### 12.3.2.2 INSTRUCTION LINK DEFINITION (FRAMEWORK CAPABILITY)

Attribute	Type	Comment
Link text	Text	<p>Text to be used as link. For any text enclosed in curly brackets within the instruction text you can define a link with the <b>Link URL</b> attribute. Including the brackets in the link text is optional. Maximum length is 80 characters.</p>
Link URL	Text	<p>URL of the file to be displayed. The link opens the external application assigned to the file type by the operating system. Maximum length is 256 characters.</p>

### 12.3.3 Basic Parameters

#### 12.3.3.1 GID-2670755 INSTRUCTION (SR0526.8.1)

Attribute	Type	Comment
Text	HTML text	<p>Instruction text to be displayed. <b>Restriction:</b> Maximum length is 4000 characters (including HTML tags).</p>

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

#### 12.3.3.2 GID-2670756 MODE (SR0526.8.5)

Attribute	Type	Comment
Mode	Choice list	<p>Defines the processing mode. <b>Manual completion</b> (default): Operator confirms the phase. <b>Automatic completion</b>: Phase is automatically completed after the parameter values have been retrieved successfully from the DCS.</p>

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Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

#### 12.3.3.3 GID-2670757 DCS (SR0526.8.2)

Attribute	Type	Comment
Name	String	Logical name of the DCS to be used. The available entries correspond to the entries in the <b>DCSNames</b> list. Default setting: First entry in the list. Maximum length is 255 characters.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

#### 12.3.3.4 GID-2670758 DEFINITION (SR0526.8.3)

Attribute	Type	Comment
Batch ID	String	Optional parameter to define the identifier of the batch to be used for data retrieval. Maximum length is 250 characters.
Unit ID	String	Optional parameter to define the identifier of the unit to be used. Maximum length is 250 characters.
Module IDs	Text (structured)	Optional parameter to define the list of equipment module IDs and control module IDs. Maximum length is 2000 characters.
Product ID	String	Optional parameter to define the identifier of the product. Maximum length is 250 characters.
Recipe ID	String	Optional parameter to define the identifier of the recipe. Maximum length is 250 characters.

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Attribute	Type	Comment
Data source	Choice list	Optional parameter to define how the message is processed in the Manufacturing Service Bus (MSB) (e.g., SMAC, ULDL, RMS). Maximum length is 250 characters. The available entries correspond to the entries in the <b>DCSDataSource</b> list.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

#### 12.3.4 Configuration of User-triggered Exceptions

##### 12.3.4.1 GID-2670759 OVERRIDE DCS PARAMETER VALUE (SR0526.8.4)

Attribute	Type	Comment
Risk assessment	Choice list	Defines the risk level of the exception and thus controls the related signature privilege. Available settings: <b>None</b> , <b>Low</b> , <b>Low (mandatory comment)</b> , <b>Medium</b> , <b>Medium (mandatory comment)</b> , <b>High</b> , <b>High (mandatory comment)</b> . Default setting: <b>High</b> , defined by the <b>DefaultRiskClassForPhaseProcessParameter</b> configuration key.
Exception text	Text	Defines the exception description used during exception handling and within the batch record. Maximum length is 256 characters.

See also **Override DCS parameter value (SR0526.3.1.1)** user-triggered exception ([GID-2670836](#))

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

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### **12.3.5 Boolean Value Bundle**

#### **12.3.5.1 [BOOLEAN] BUNDLE PROCESS PARAMETERS ()**

For the master process parameter of a bundle, its internal identifier is populated from the bundle identifier.

For all other process parameters of the bundle, their internal identifier is a concatenation of the bundle identifier and the process parameter name.

This framework capability refers to **Bundle Process Parameters (SR3146.9.7.4.1)** in "Functional Requirement Specification Recipe and Workflow Management" [A4] ([GID-2667776](#)).

#### **12.3.5.2 GID-2670761 [BOOLEAN] MASTER (BUNDLE IDENTIFIER) (SR0526.8.6)**

Attribute	Type	Comment
Parameter	String	Defines the identifier of the parameter to be read. Maximum length is 200 characters.
Parameter description	String	Defines an alias for the parameter. Maximum length is 200 characters.
Parameter path	String	Defines the path of the parameter. Maximum length is 400 characters.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

#### **12.3.5.3 GID-2670762 [BOOLEAN] EXPECTED VALUE VISIBLE IN PEC (SR0526.8.9)**

Attribute	Type	Comment
Enabled	Flag	Controls if the expected value is visible during execution. Default setting: Yes

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

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#### 12.3.5.4 GID-2670763 [BOOLEAN] PARAMETER TYPE (SR0526.8.10)

Attribute	Type	Comment
Parameter type	Choice list	<p>Optional parameter to define the type of the parameter when the same parameter identifier is available for different types.</p> <p>The available settings (<b>Prompt</b>, <b>Report</b>, <b>Recipe</b>, <b>Status change</b>) correspond to the entries in the <b>DCSParameterType</b> list.</p> <p>Maximum length is 200 characters.</p>

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

#### 12.3.5.5 CONFIGURATION OF SYSTEM-TRIGGERED EXCEPTIONS

#### 12.3.5.6 GID-2670765 [BOOLEAN] EXPECTED VALUE CONFIGURATION (SR0526.8.7)

Attribute	Type	Comment
Enabled	Flag	<p>Controls if a check is performed. If so, ensure that the <b>Value</b> attribute of the <b>Expected value definition</b> process parameter (<a href="#">GID-2670766</a>) is set. If it is not set, the validation will fail.</p> <p>Default setting: <b>No</b>.</p>
Risk assessment	Choice list	<p>Defines the risk level of the exception and thus controls the related signature privilege.</p> <p>Available settings: <b>None</b>, <b>Low</b>, <b>Low (mandatory comment)</b>, <b>Medium</b>, <b>Medium (mandatory comment)</b>, <b>High</b>, <b>High (mandatory comment)</b>.</p> <p>Default setting: <b>High</b>.</p>
Exception text	Text	<p>Defines the exception description used during exception handling and within the batch record.</p> <p>Maximum length is 250 characters.</p>

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See also Limit violation (SR0526.3.2.1) system-triggered exception ([GID-2670833](#)).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

#### 12.3.5.7 GID-2670766 [BOOLEAN] EXPECTED VALUE DEFINITION (SR0526.8.8)

Attribute	Type	Comment
Value	Choice list	Defines the expected value. Available settings: N/A, Yes, No. Default setting: N/A.

See also Limit violation (SR0526.3.2.1) system-triggered exception ([GID-2670833](#)).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

#### 12.3.6 Boolean Value (Extended) Bundle

##### 12.3.6.1 [BOOLEAN EXTENDED] BUNDLE PROCESS PARAMETERS (FRAMEWORK CAPABILITY)

For the master process parameter of a bundle, its internal identifier is populated from the bundle identifier.

For all other process parameters of the bundle, their internal identifier is a concatenation of the bundle identifier and the process parameter name.

This framework capability refers to **Bundle Process Parameters (SR3146.9.7.4.1)** in "Functional Requirement Specification Recipe and Workflow Management" [A4] ([GID-2667776](#)).

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#### 12.3.6.2 GID-2670768 [BOOLEAN EXTENDED] MASTER (BUNDLE IDENTIFIER) (SR0526.8.11)

Attribute	Type	Comment
Parameter	String	Defines the identifier of the parameter to be read on the DCS. Maximum length is 200 characters.
Parameter for description	String	Defines the name of the description parameter on the DCS. Maximum length is 200 characters.
Common path	String	Defines the path of all parameters of the bundle on the DCS. Maximum length is 400 characters.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

#### 12.3.6.3 GID-2670769 [BOOLEAN EXTENDED] EXPECTED VALUE VISIBLE IN PEC (SR0526.8.14)

Attribute	Type	Comment
Enabled	Flag	Controls if the expected value is visible during execution. Default setting: Yes

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

#### 12.3.6.4 GID-2670770 [BOOLEAN EXTENDED] PARAMETER TYPE (SR0526.8.15)

Attribute	Type	Comment
Parameter type	Choice list	Optional parameter to define the type of the parameter when the same parameter identifier is available for different types. The available settings ( <b>Prompt</b> , <b>Report</b> , <b>Recipe</b> , <b>Status change</b> ) correspond to the entries in the <b>DCSParameterType</b> list. Maximum length is 200 characters.

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Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

#### 12.3.6.5 CONFIGURATION OF SYSTEM-TRIGGERED EXCEPTIONS

##### 12.3.6.5.1 GID-2671665 [BOOLEAN EXTENDED] EXPECTED VALUE CONFIGURATION (SR0526.8.12)

Attribute	Type	Comment
Enabled	Flag	Controls if a check is performed. If so, ensure that the <b>Value</b> attribute of the <b>Expected value definition parameter</b> ) process parameter ( <a href="#">(GID-2671666)</a> is set. If it is not set, the validation will fail. Default setting: <b>No</b> .
Risk assessment	Choice list	Defines the risk level of the exception and thus controls the related signature privilege. Available settings: <b>None</b> , <b>Low</b> , <b>Low (mandatory comment)</b> , <b>Medium</b> , <b>Medium (mandatory comment)</b> , <b>High</b> , <b>High (mandatory comment)</b> . Default setting: <b>High</b> .
Exception text	Text	Defines the exception description used during exception handling and within the batch record. Maximum length is 250 characters.

See also Limit violation (SR0526.3.2.1) system-triggered exception ([\(GID-2670833\)](#))

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

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#### 12.3.6.5.2 GID-2671666 [BOOLEAN EXTENDED] EXPECTED VALUE DEFINITION PARAMETER (SR0526.8.13)

Attribute	Type	Comment
Value	String	Defines the name of the expected value parameter on the DCS. Maximum length is 200 characters.

See also Limit violation (SR0526.3.2.1) system-triggered exception ([GID-2670833](#))

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

#### 12.3.7 Duration Value Bundle

##### 12.3.7.1 [DURATION] BUNDLE PROCESS PARAMETERS (FRAMEWORK CAPABILITY)

For the master process parameter of a bundle, its internal identifier is populated from the bundle identifier.

For all other process parameters of the bundle, their internal identifier is a concatenation of the bundle identifier and the process parameter name.

This framework capability refers to **Bundle Process Parameters (SR3146.9.7.4.1)** in "Functional Requirement Specification Recipe and Workflow Management" [A4] ([GID-2667776](#)).

##### 12.3.7.2 GID-2670773 [DURATION] MASTER (BUNDLE IDENTIFIER) (SR0526.8.16)

Attribute	Type	Comment
Parameter	String	Defines the identifier of the parameter to be read. Maximum length is 200 characters.
Parameter description	String	Defines an alias for the parameter. Maximum length is 200 characters.
Parameter path	String	Defines the path of the parameter. Maximum length is 400 characters.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

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#### 12.3.7.3 GID-2670774 [DURATION] LIMITS VISIBLE IN PEC (SR0526.8.20)

Attribute	Type	Comment
Enabled	Flag	Controls if the limits are visible during execution. Default setting: Yes

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

#### 12.3.7.4 GID-2670775 [DURATION] PARAMETER TYPE (SR0526.8.21)

Attribute	Type	Comment
Parameter type	Choice list	Optional parameter to define the type of the parameter when the same parameter identifier is available for different types. The available settings ( <b>Prompt</b> , <b>Report</b> , <b>Recipe</b> , <b>Status change</b> ) correspond to the entries in the <b>DCSParameterType</b> list. Maximum length is 200 characters.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

#### 12.3.7.5 CONFIGURATION OF SYSTEM-TRIGGERED EXCEPTIONS

#### 12.3.7.6 GID-2670777 [DURATION] L-H CONFIGURATION (SR0526.8.17)

If the checks are activated for the available limit ranges, the checks are performed in the following order:

1. LL-HH (defined with the **LL-HH configuration (SR0526.8.18)** process parameter ([GID-2670778](#)))
2. L-H

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Attribute	Type	Comment
Enabled	Flag	Controls if a check is performed. If so, ensure that the L limit or H limit attributes of the Limit definition process parameter ( <a href="#">GID-2670779</a> ) are set. If they are not set, the validation will fail. Default setting: No.
Risk assessment	Choice list	Defines the risk level of the exception and thus controls the related signature privilege. Available settings: None, Low, Low (mandatory comment), Medium, Medium (mandatory comment), High, High (mandatory comment). Default setting: High.
Exception text	Text	Defines the exception description used during exception handling and within the batch record. Maximum length is 250 characters.

See also **Limit violation (SR0526.3.2.1)** system-triggered exception ([GID-2670833](#))

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

#### 12.3.7.7 GID-2670778 [DURATION] LL-HH CONFIGURATION (SR0526.8.18)

If the checks are activated for the available limit ranges, the checks are performed in the following order:

1. LL-HH
2. L-H (defined with the **L-H configuration (SR0526.8.17)** process parameter (GID-2495717))

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Attribute	Type	Comment
Enabled	Flag	Controls if a check is performed. If so, ensure that the <b>LL limit</b> or <b>HH limit</b> attributes of the <b>Limit definition</b> process parameter ( <a href="#">GID-2670779</a> ) are set. If they are not set, the validation will fail. Default setting: <b>No</b> .
Risk assessment	Choice list	Defines the risk level of the exception and thus controls the related signature privilege. Available settings: <b>None</b> , <b>Low</b> , <b>Low (mandatory comment)</b> , <b>Medium</b> , <b>Medium (mandatory comment)</b> , <b>High</b> , <b>High (mandatory comment)</b> . Default setting: <b>High</b> .
Exception text	Text	Defines the exception description used during exception handling and within the batch record. Maximum length is 250 characters.

See also **Limit violation (SR0526.3.2.1)** system-triggered exception ([GID-2670833](#)).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

### 12.3.7.8 GID-2670779 [DURATION] LIMIT DEFINITION (SR0526.8.19)

The following rule applies to the attributes:

- LL limit < L limit < H limit < HH limit

Attribute	Type	Comment
LL limit	Duration	Define the values of the lower limits (including the values themselves).
L limit	Duration	
H limit	Duration	Define the values of the upper limits (including the values themselves).
HH limit	Duration	

See also Limit violation (SR0526.3.2.1) system-triggered exception ([GID-2670833](#))

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

### 12.3.8 Duration Value (Extended) Bundle

#### 12.3.8.1 [DURATION EXTENDED] BUNDLE PROCESS PARAMETERS (FRAMEWORK CAPABILITY)

For the master process parameter of a bundle, its internal identifier is populated from the bundle identifier.

For all other process parameters of the bundle, their internal identifier is a concatenation of the bundle identifier and the process parameter name.

This framework capability refers to **Bundle Process Parameters (SR3146.9.7.4.1)** in "Functional Requirement Specification Recipe and Workflow Management" [A4] ([GID-2667776](#))

#### 12.3.8.2 GID-2670781 [DURATION EXTENDED] MASTER (BUNDLE IDENTIFIER) (SR0526.8.22)

Attribute	Type	Comment
Parameter	String	Defines the identifier of the parameter to be read on the DCS. Maximum length is 200 characters.
Parameter for description	String	Defines the name of the description parameter on the DCS. Maximum length is 200 characters.

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Attribute	Type	Comment
Common path	String	Defines the path of all parameters of the bundle on the DCS. Maximum length is 400 characters.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

#### 12.3.8.3 GID-2670782 [DURATION EXTENDED] LIMITS VISIBLE IN PEC (SR0526.8.26)

Attribute	Type	Comment
Enabled	Flag	Controls if the limits are visible during execution. Default setting: Yes

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

#### 12.3.8.4 GID-2670783 [DURATION EXTENDED] PARAMETER TYPE (SR0526.8.27)

Attribute	Type	Comment
Parameter type	Choice list	Optional parameter to define the type of the parameter when the same parameter identifier is available for different types. The available settings ( <b>Prompt</b> , <b>Report</b> , <b>Recipe</b> , <b>Status change</b> ) correspond to the entries in the <b>DCSParameterType</b> list. Maximum length is 200 characters.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

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### 12.3.8.5 CONFIGURATION OF SYSTEM-TRIGGERED EXCEPTIONS

### 12.3.8.6 GID-2670785 [DURATION EXTENDED] L-H CONFIGURATION (SR0526.8.23)

If the checks are activated for the available limit ranges, the checks are performed in the following order:

1. LL-HH (defined with the **LL-HH configuration (SR0526.8.24)** process parameter ([GID-2670786](#)))
2. L-H

Attribute	Type	Comment
Enabled	Flag	Controls if a check is performed. If so, ensure that the <b>L limit</b> or <b>H limit</b> attributes of the <b>Limit definition parameters</b> process parameter ( <a href="#">GID-2670787</a> ) are set. If they are not set, the validation will fail. Default setting: <b>No</b> .
Risk assessment	Choice list	Defines the risk level of the exception and thus controls the related signature privilege. Available settings: <b>None</b> , <b>Low</b> , <b>Low (mandatory comment)</b> , <b>Medium</b> , <b>Medium (mandatory comment)</b> , <b>High</b> , <b>High (mandatory comment)</b> . Default setting: <b>High</b> .
Exception text	Text	Defines the exception description used during exception handling and within the batch record. Maximum length is 250 characters.

See also **Limit violation (SR0526.3.2.1)** system-triggered exception ([GID-2670833](#))

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

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#### 12.3.8.7 GID-2670786 [DURATION EXTENDED] LL-HH CONFIGURATION (SR0526.8.24)

If the checks are activated for the available limit ranges, the checks are performed in the following order:

1. LL-HH

2. L-H (defined with the **L-H configuration (SR0526.8.23)** process parameter ([GID-2670785](#)))

Attribute	Type	Comment
Enabled	Flag	Controls if a check is performed. If so, ensure that the LL limit or HH limit attributes of the <b>Limit definition parameters</b> process parameter ( <a href="#">GID-2670787</a> ) are set. If they are not set, the validation will fail. Default setting: No.
Risk assessment	Choice list	Defines the risk level of the exception and thus controls the related signature privilege. Available settings: None, Low, Low (mandatory comment), Medium, Medium (mandatory comment), High, High (mandatory comment). Default setting: High.
Exception text	Text	Defines the exception description used during exception handling and within the batch record. Maximum length is 250 characters.

See also **Limit violation (SR0526.3.2.1)** system-triggered exception ([GID-2670833](#))

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

#### 12.3.8.8 GID-2670787 [DURATION EXTENDED] LIMIT DEFINITION PARAMETERS (SR0526.8.25)

The following rule applies to the attributes:

- LL limit < L limit < H limit < HH limit

Attribute	Type	Comment
Parameter for LL limit	String	Define the names of the lower limits parameters on the DCS. Maximum length is 200 characters.
Parameter for L limit	String	Maximum length is 200 characters.
Parameter for H limit	String	Define the names of the upper limits parameters on the DCS. Maximum length is 200 characters.
Parameter for HH limit	String	Maximum length is 200 characters.

See also **Limit violation (SR0526.3.2.1)** system-triggered exception ([GID-2670833](#))

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

### 12.3.9 Numeric Value Bundle

#### 12.3.9.1 [NUMERIC] BUNDLE PROCESS PARAMETERS (FRAMEWORK CAPABILITY)

For the master process parameter of a bundle, its internal identifier is populated from the bundle identifier.

For all other process parameters of the bundle, their internal identifier is a concatenation of the bundle identifier and the process parameter name.

This framework capability refers to **Bundle Process Parameters (SR3146.9.7.4.1)** in "Functional Requirement Specification Recipe and Workflow Management" [A4] ([GID-2667776](#))

#### 12.3.9.2 GID-2670789 [NUMERIC] MASTER (BUNDLE IDENTIFIER) (SR0526.8.28)

Attribute	Type	Comment
Parameter	String	Defines the identifier of the parameter to be read. Maximum length is 200 characters.
Parameter description	String	Defines an alias for the parameter. Maximum length is 200 characters.
Parameter path	String	Defines the path of the parameter. Maximum length is 400 characters.

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Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

#### 12.3.9.3 GID-2670790 [NUMERIC] LIMITS VISIBLE IN PEC (SR0526.8.32)

Attribute	Type	Comment
Enabled	Flag	Controls if the limits are visible during execution. Default setting: Yes

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

#### 12.3.9.4 GID-2670791 [NUMERIC] PARAMETER TYPE (SR0526.8.33)

Attribute	Type	Comment
Parameter type	Choice list	Optional parameter to define the type of the parameter when the same parameter identifier is available for different types. The available settings ( <b>Prompt</b> , <b>Report</b> , <b>Recipe</b> , <b>Status change</b> ) correspond to the entries in the <b>DCSParameterType</b> list. Maximum length is 200 characters.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

#### 12.3.9.5 CONFIGURATION OF SYSTEM-TRIGGERED EXCEPTIONS

#### 12.3.9.6 GID-2670793 [NUMERIC] L-H CONFIGURATION (SR0526.8.29)

If the checks are activated for the available limit ranges, the checks are performed in the following order:

1. LL-HH (defined with the **LL-HH configuration (SR0526.8.30)** process parameter ([GID-2670794](#)))
2. L-H

Attribute	Type	Comment
Enabled	Flag	Controls if a check is performed. If so, ensure that the L limit or H limit attributes of the Limit definition process parameter ( <a href="#">GID-2670795</a> ) are set. If they are not set, the validation will fail. Default setting: No.
Risk assessment	Choice list	Defines the risk level of the exception and thus controls the related signature privilege. Available settings: None, Low, Low (mandatory comment), Medium, Medium (mandatory comment), High, High (mandatory comment). Default setting: High.
Exception text	Text	Defines the exception description used during exception handling and within the batch record. Maximum length is 250 characters.

See also Limit violation (SR0526.3.2.1) system-triggered exception ([GID-2670833](#)).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

#### 12.3.9.7 GID-2670794 [NUMERIC] LL-HH CONFIGURATION (SR0526.8.30)

If the checks are activated for the available limit ranges, the checks are performed in the following order:

1. LL-HH
2. L-H (defined with the **L-H configuration (SR0526.8.29)** process parameter ([GID-2670793](#)))

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Attribute	Type	Comment
Enabled	Flag	Controls if a check is performed. If so, ensure that the <b>LL limit</b> or <b>HH limit</b> attributes of the <b>Limit definition</b> process parameter ( <a href="#">(GID-2670795)</a> ) are set. If they are not set, the validation will fail. Default setting: <b>No</b> .
Risk assessment	Choice list	Defines the risk level of the exception and thus controls the related signature privilege. Available settings: <b>None</b> , <b>Low</b> , <b>Low (mandatory comment)</b> , <b>Medium</b> , <b>Medium (mandatory comment)</b> , <b>High</b> , <b>High (mandatory comment)</b> . Default setting: <b>High</b> .
Exception text	Text	Defines the exception description used during exception handling and within the batch record. Maximum length is 250 characters.

See also **Limit violation (SR0526.3.2.1)** system-triggered exception ([\(GID-2670833\)](#))

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

#### 12.3.9.8 GID-2670795 [NUMERIC] LIMIT DEFINITION (SR0526.8.31)

The following rule applies to the attributes:

- LL limit < L limit < H limit < HH limit

Attribute	Type	Comment
LL limit	BigDecimal (Double, Float, Integer)	Define the values of the lower limits (including the values themselves).
L limit	BigDecimal (Double, Float, Integer)	
H limit	BigDecimal (Double, Float, Integer)	Define the values of the upper limits (including the values themselves).
HH limit	BigDecimal (Double, Float, Integer)	

See also **Limit violation (SR0526.3.2.1)** system-triggered exception [\(GID-2670833\)](#)

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

### 12.3.10 *Numeric Value (Extended) Bundle*

#### 12.3.10.1 [NUMERIC EXTENDED] BUNDLE PROCESS PARAMETERS (FRAMEWORK CAPABILITY)

For the master process parameter of a bundle, its internal identifier is populated from the bundle identifier.

For all other process parameters of the bundle, their internal identifier is a concatenation of the bundle identifier and the process parameter name.

This framework capability refers to **Bundle Process Parameters (SR3146.9.7.4.1)** in "Functional Requirement Specification Recipe and Workflow Management" [A4] [\(GID-2667776\)](#)

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#### 12.3.10.2 GID-2670797 [NUMERIC EXTENDED] MASTER (BUNDLE IDENTIFIER) (SR0526.8.34)

Attribute	Type	Comment
Parameter	String	Defines the identifier of the parameter to be read on the DCS. Maximum length is 200 characters.
Parameter for description	String	Defines the name of the description parameter on the DCS. Maximum length is 200 characters.
Common path	String	Defines the path of all parameters of the bundle on the DCS. Maximum length is 400 characters.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

#### 12.3.10.3 GID-2670798 [NUMERIC EXTENDED] LIMITS VISIBLE IN PEC (SR0526.8.38)

Attribute	Type	Comment
Enabled	Flag	Controls if the limits are visible during execution. Default setting: Yes

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

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#### 12.3.10.4 GID-2670799 [NUMERIC EXTENDED] PARAMETER TYPE (SR0526.8.39)

Attribute	Type	Comment
Parameter type	Choice list	<p>Optional parameter to define the type of the parameter when the same parameter identifier is available for different types.</p> <p>The available settings (<b>Prompt</b>, <b>Report</b>, <b>Recipe</b>, <b>Status change</b>) correspond to the entries in the <b>DCSParameterType</b> list.</p> <p>Maximum length is 200 characters.</p>

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

#### 12.3.10.5 CONFIGURATION OF SYSTEM-TRIGGERED EXCEPTIONS

#### 12.3.10.6 GID-2670801 [NUMERIC EXTENDED] L-H CONFIGURATION (SR0526.8.35)

If the checks are activated for the available limit ranges, the checks are performed in the following order:

1. LL-HH (defined with the **LL-HH configuration (SR0526.8.36)** process parameter ([GID-2670802](#)))
2. L-H

Attribute	Type	Comment
Enabled	Flag	<p>Controls if a check is performed. If so, ensure that the L limit or H limit attributes of the <b>Limit definition parameters</b> process parameter (<a href="#">GID-2670803</a>) are set. If they are not set, the validation will fail.</p> <p>Default setting: No.</p>
Risk assessment	Choice list	<p>Defines the risk level of the exception and thus controls the related signature privilege.</p> <p>Available settings: <b>None</b>, <b>Low</b>, <b>Low (mandatory comment)</b>, <b>Medium</b>, <b>Medium (mandatory comment)</b>, <b>High</b>, <b>High (mandatory comment)</b>.</p> <p>Default setting: High.</p>

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Attribute	Type	Comment
Exception text	Text	Defines the exception description used during exception handling and within the batch record. Maximum length is 250 characters.

See also **Limit violation (SR0526.3.2.1)** system-triggered exception ([\(GID-2670833\)](#))

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

#### 12.3.10.7 GID-2670802 [NUMERIC EXTENDED] LL-HH CONFIGURATION (SR0526.8.36)

If the checks are activated for the available limit ranges, the checks are performed in the following order:

1. LL-HH
2. L-H (defined with the **L-H configuration (SR0526.8.35)** process parameter ([\(GID-2670801\)](#)))

Attribute	Type	Comment
Enabled	Flag	Controls if a check is performed. If so, ensure that the <b>LL</b> limit or <b>HH</b> limit attributes of the <b>Limit definition parameters</b> process parameter ( <a href="#">(GID-2670803)</a> ) are set. If they are not set, the validation will fail. Default setting: No.
Risk assessment	Choice list	Defines the risk level of the exception and thus controls the related signature privilege. Available settings: <b>None</b> , <b>Low</b> , <b>Low (mandatory comment)</b> , <b>Medium</b> , <b>Medium (mandatory comment)</b> , <b>High</b> , <b>High (mandatory comment)</b> . Default setting: High.
Exception text	Text	Defines the exception description used during exception handling and within the batch record. Maximum length is 250 characters.

See also Limit violation (SR0526.3.2.1) system-triggered exception ([GID-2670833](#))

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

#### 12.3.10.8 GID-2670803 [NUMERIC EXTENDED] LIMIT DEFINITION PARAMETERS (SR0526.8.37)

The following rule applies to the attributes:

- LL limit < L limit < H limit < HH limit

Attribute	Type	Comment
Parameter for LL limit	String	Define the names of the lower limits parameters on the DCS. Maximum length is 200 characters.
Parameter for L limit	String	Maximum length is 200 characters.
Parameter for H limit	String	Define the names of the upper limits parameters on the DCS. Maximum length is 200 characters.
Parameter for HH limit	String	Maximum length is 200 characters.

See also Limit violation (SR0526.3.2.1) system-triggered exception ([GID-2670833](#)).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

#### 12.3.11 *String Value Bundle*

##### 12.3.11.1 [STRING] BUNDLE PROCESS PARAMETERS (FRAMEWORK CAPABILITY)

For the master process parameter of a bundle, its internal identifier is populated from the bundle identifier.

For all other process parameters of the bundle, their internal identifier is a concatenation of the bundle identifier and the process parameter name.

This framework capability refers to **Bundle Process Parameters (SR3146.9.7.4.1)** in "Functional Requirement Specification Recipe and Workflow Management" [A4] ([GID-2667776](#))

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#### 12.3.11.2 GID-2670805 [STRING] MASTER (BUNDLE IDENTIFIER) (SR0526.8.40)

Attribute	Type	Comment
Parameter	String	Defines the identifier of the parameter to be read. Maximum length is 200 characters.
Parameter description	String	Defines an alias for the parameter. Maximum length is 200 characters.
Parameter path	String	Defines the path of the parameter. Maximum length is 400 characters.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

#### 12.3.11.3 GID-2670806 [STRING] EXPECTED VALUE VISIBLE IN PEC (SR0526.8.43)

Attribute	Type	Comment
Enabled	Flag	Controls if the expected value is visible during execution. Default setting: Yes

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

#### 12.3.11.4 GID-2670807 [STRING] PARAMETER TYPE (SR0526.8.44)

Attribute	Type	Comment
Parameter type	Choice list	Optional parameter to define the type of the parameter when the same parameter identifier is available for different types. The available settings ( <b>Prompt</b> , <b>Report</b> , <b>Recipe</b> , <b>Status change</b> ) correspond to the entries in the <b>DCSPParameterType</b> list. Maximum length is 200 characters.

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Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

#### 12.3.11.5 CONFIGURATION OF SYSTEM-TRIGGERED EXCEPTIONS

#### 12.3.11.6 GID-2670809 [STRING] EXPECTED VALUE CONFIGURATION (SR0526.8.41)

Attribute	Type	Comment
Enabled	Flag	Controls if a check is performed. If so, ensure that the <b>Value</b> attribute of the <b>Expected value definition</b> process parameter ( <a href="#">GID-2670810</a> ) is set. If it is not set, the validation will fail. Default setting: <b>No</b> .
Risk assessment	Choice list	Defines the risk level of the exception and thus controls the related signature privilege. Available settings: <b>None</b> , <b>Low</b> , <b>Low (mandatory comment)</b> , <b>Medium</b> , <b>Medium (mandatory comment)</b> , <b>High</b> , <b>High (mandatory comment)</b> . Default setting: <b>High</b> .
Exception text	Text	Defines the exception description used during exception handling and within the batch record. Maximum length is 250 characters.

See also **Limit violation (SR0526.3.2.1)** system-triggered exception [\(GID-2670833\)](#).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

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#### 12.3.11.7 GID-2670810 [STRING] EXPECTED VALUE DEFINITION (SR0526.8.42)

Attribute	Type	Comment
Value	Text	Defines the expected value. Maximum length is 2000 characters.

See also **Limit violation (SR0526.3.2.1)** system-triggered exception ([GID-2670833](#)).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

#### 12.3.12 String Value (Extended) Bundle

[String Extended] Bundle process parameters (Framework capability)

For the master process parameter of a bundle, its internal identifier is populated from the bundle identifier.

For all other process parameters of the bundle, their internal identifier is a concatenation of the bundle identifier and the process parameter name.

This framework capability refers to **Bundle Process Parameters (SR3146.9.7.4.1)** in "Functional Requirement Specification Recipe and Workflow Management" [A4] ([GID-2667776](#))

#### 12.3.12.1 GID-2670811 [STRING EXTENDED] MASTER (BUNDLE IDENTIFIER) (SR0526.8.45)

Attribute	Type	Comment
Parameter	String	Defines the identifier of the parameter to be read on the DCS. Maximum length is 200 characters.
Parameter for description	String	Defines the name of the description parameter on the DCS. Maximum length is 200 characters.
Common path	String	Defines the path of all parameters of the bundle on the DCS. Maximum length is 400 characters.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

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### 12.3.12.2 GID-2670812 [STRING EXTENDED] EXPECTED VALUE VISIBLE IN PEC (SR0526.8.48)

Attribute	Type	Comment
Enabled	Flag	Controls if the expected value is visible during execution. Default setting: Yes

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

### 12.3.12.3 GID-2670813 [STRING EXTENDED] PARAMETER TYPE (SR0526.8.49)

Attribute	Type	Comment
Parameter type	Choice list	Optional parameter to define the type of the parameter when the same parameter identifier is available for different types. The available settings ( <b>Prompt</b> , <b>Report</b> , <b>Recipe</b> , <b>Status change</b> ) correspond to the entries in the <b>DCSParameterType</b> list. Maximum length is 200 characters.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

### 12.3.12.4 CONFIGURATION OF SYSTEM-TRIGGERED EXCEPTIONS

### 12.3.12.5 GID-2670815 [STRING EXTENDED] EXPECTED VALUE CONFIGURATION (SR0526.8.46)

Attribute	Type	Comment
Enabled	Flag	Controls if a check is performed. If so, ensure that the <b>Value</b> attribute of the <b>Expected value definition parameter</b> process parameter ( <a href="#">GID-2670816</a> ) is set. If it is not set, the validation will fail. Default setting: No.

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Attribute	Type	Comment
Risk assessment	Choice list	Defines the risk level of the exception and thus controls the related signature privilege. Available settings: <b>None</b> , <b>Low</b> , <b>Low (mandatory comment)</b> , <b>Medium</b> , <b>Medium (mandatory comment)</b> , <b>High</b> , <b>High (mandatory comment)</b> . Default setting: <b>High</b> .
Exception text	Text	Defines the exception description used during exception handling and within the batch record. Maximum length is 250 characters.

See also Limit violation (SR0526.3.2.1) system-triggered exception [\(GID-2670833\)](#).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

#### 12.3.12.6 GID-2670816 [STRING EXTENDED] EXPECTED VALUE DEFINITION PARAMETER (SR0526.8.47)

Attribute	Type	Comment
Value	String	Defines the name of the expected value parameter on the DCS. Maximum length is 200 characters. Maximum length of the return value is 2000 characters.

See also Limit violation (SR0526.3.2.1) system-triggered exception [\(GID-2670833\)](#).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

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### 12.3.13 *Timestamp Value Bundle*

#### 12.3.13.1 [TIMESTAMP] BUNDLE PROCESS PARAMETERS (FRAMEWORK CAPABILITY)

For the master process parameter of a bundle, its internal identifier is populated from the bundle identifier.

For all other process parameters of the bundle, their internal identifier is a concatenation of the bundle identifier and the process parameter name.

This framework capability refers to **Bundle Process Parameters (SR3146.9.7.4.1)** in "Functional Requirement Specification Recipe and Workflow Management" [A4] ([GID-2667776](#))

#### 12.3.13.2 GID-2670818 [TIMESTAMP] MASTER (BUNDLE IDENTIFIER) (SR0526.8.50)

Attribute	Type	Comment
Parameter	String	Defines the identifier of the parameter to be read. Maximum length is 200 characters.
Parameter description	String	Defines an alias for the parameter. Maximum length is 200 characters.
Parameter path	String	Defines the path of the parameter. Maximum length is 400 characters.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

#### 12.3.13.3 GID-2670819 [TIMESTAMP] LIMITS VISIBLE IN PEC (SR0526.8.54)

Attribute	Type	Comment
Enabled	Flag	Controls if the limits are visible during execution. Default setting: Yes

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

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#### 12.3.13.4 GID-2670820 [TIMESTAMP] PARAMETER TYPE (SR0526.8.55)

Attribute	Type	Comment
Parameter type	Choice list	<p>Optional parameter to define the type of the parameter when the same parameter identifier is available for different types.</p> <p>The available settings (<b>Prompt</b>, <b>Report</b>, <b>Recipe</b>, <b>Status change</b>) correspond to the entries in the <b>DCSParameterType</b> list.</p> <p>Maximum length is 200 characters.</p>

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

#### 12.3.13.5 CONFIGURATION OF SYSTEM-TRIGGERED EXCEPTIONS

#### 12.3.13.6 GID-2670822 [TIMESTAMP] L-H CONFIGURATION (SR0526.8.51)

If the checks are activated for the available limit ranges, the checks are performed in the following order:

1. LL-HH (defined with the **LL-HH configuration (SR0526.8.52)** process parameter ([GID-2670823](#)))
2. L-H

Attribute	Type	Comment
Enabled	Flag	<p>Controls if a check is performed. If so, ensure that the <b>L limit</b> or <b>H limit</b> attributes of the <b>Limit definition</b> process parameter (<a href="#">GID-2670824</a>) are set. If they are not set, the validation will fail.</p> <p>Default setting: <b>No</b>.</p>

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Attribute	Type	Comment
Risk assessment	Choice list	Defines the risk level of the exception and thus controls the related signature privilege. Available settings: <b>None</b> , <b>Low</b> , <b>Low (mandatory comment)</b> , <b>Medium</b> , <b>Medium (mandatory comment)</b> , <b>High</b> , <b>High (mandatory comment)</b> . Default setting: <b>High</b> .
Exception text	Text	Defines the exception description used during exception handling and within the batch record. Maximum length is 250 characters.

See also **Limit violation (SR0526.3.2.1)** system-triggered exception ([GID-2670833](#)).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

#### 12.3.13.7 GID-2670823 [TIMESTAMP] LL-HH CONFIGURATION (SR0526.8.52)

If the checks are activated for the available limit ranges, the checks are performed in the following order:

1. LL-HH
2. L-H (defined with the **L-H configuration (SR0526.8.51)** process parameter ([GID-2670822](#)))

Attribute	Type	Comment
Enabled	Flag	Controls if a check is performed. If so, ensure that the <b>LL limit</b> or <b>HH limit</b> attributes of the <b>Limit definition</b> process parameter ( <a href="#">GID-2670824</a> ) are set. If they are not set, the validation will fail. Default setting: <b>No</b> .

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Attribute	Type	Comment
Risk assessment	Choice list	Defines the risk level of the exception and thus controls the related signature privilege. Available settings: <b>None</b> , <b>Low</b> , <b>Low (mandatory comment)</b> , <b>Medium</b> , <b>Medium (mandatory comment)</b> , <b>High</b> , <b>High (mandatory comment)</b> . Default setting: <b>High</b> .
Exception text	Text	Defines the exception description used during exception handling and within the batch record. Maximum length is 250 characters.

See also **Limit violation (SR0526.3.2.1)** system-triggered exception ([GID-2670833](#)).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

#### 12.3.13.8 GID-2670824 [TIMESTAMP] LIMIT DEFINITION (SR0526.8.53)

The following rule applies to the attributes:

- LL limit < L limit < H limit < HH limit

Attribute	Type	Comment
LL limit	Timestamp	Define the values of the lower limits (including the values themselves).
L limit	Timestamp	
H limit	Timestamp	Define the values of the upper limits (including the values themselves).
HH limit	Timestamp	

See also **Limit violation (SR0526.3.2.1)** system-triggered exception ([GID-2670833](#)).

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Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

### 12.3.14 *Timestamp Value (Extended) Bundle*

#### 12.3.14.1 [TIMESTAMP EXTENDED] BUNDLE PROCESS PARAMETERS (FRAMEWORK CAPABILITY)

For the master process parameter of a bundle, its internal identifier is populated from the bundle identifier.

For all other process parameters of the bundle, their internal identifier is a concatenation of the bundle identifier and the process parameter name.

This framework capability refers to **Bundle Process Parameters (SR3146.9.7.4.1)** in "Functional Requirement Specification Recipe and Workflow Management" [A4] ([GID-2667776](#))

#### 12.3.14.2 GID-2670826 [TIMESTAMP EXTENDED] MASTER (BUNDLE IDENTIFIER) (SR0526.8.56)

Attribute	Type	Comment
Parameter	String	Defines the identifier of the parameter to be read on the DCS. Maximum length is 200 characters.
Parameter for description	String	Defines the name of the description parameter on the DCS. Maximum length is 200 characters.
Common path	String	Defines the path of all parameters of the bundle on the DCS. Maximum length is 400 characters.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

#### 12.3.14.3 GID-2670827 [TIMESTAMP EXTENDED] LIMITS VISIBLE IN PEC (SR0526.8.60)

Attribute	Type	Comment
Enabled	Flag	Controls if the limits are visible during execution. Default setting: Yes

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Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

#### 12.3.14.4 GID-2670828 [TIMESTAMP EXTENDED] PARAMETER TYPE (SR0526.8.61)

Attribute	Type	Comment
Parameter type	Choice list	<p>Optional parameter to define the type of the parameter when the same parameter identifier is available for different types.</p> <p>The available settings (<b>Prompt</b>, <b>Report</b>, <b>Recipe</b>, <b>Status change</b>) correspond to the entries in the <b>DCSParameterType</b> list.</p> <p>Maximum length is 200 characters.</p>

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

#### 12.3.14.5 CONFIGURATION OF SYSTEM-TRIGGERED EXCEPTIONS

#### 12.3.14.6 GID-2670830 [TIMESTAMP EXTENDED] L-H CONFIGURATION (SR0526.8.57)

If the checks are activated for the available limit ranges, the checks are performed in the following order:

1. LL-HH (defined with the **LL-HH configuration (SR0526.8.38)** process parameter ([GID-2670798](#)))
2. L-H

Attribute	Type	Comment
Enabled	Flag	<p>Controls if a check is performed. If so, ensure that the <b>L limit</b> or <b>H limit</b> attributes of the <b>Limit definition parameters</b> process parameter (<a href="#">GID-2670832</a>) are set. If they are not set, the validation will fail.</p> <p>Default setting: <b>No</b>.</p>

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Attribute	Type	Comment
Risk assessment	Choice list	Defines the risk level of the exception and thus controls the related signature privilege. Available settings: <b>None</b> , <b>Low</b> , <b>Low (mandatory comment)</b> , <b>Medium</b> , <b>Medium (mandatory comment)</b> , <b>High</b> , <b>High (mandatory comment)</b> . Default setting: <b>High</b> .
Exception text	Text	Defines the exception description used during exception handling and within the batch record. Maximum length is 250 characters.

See also Limit violation (SR0526.3.2.1) system-triggered exception ([\(GID-2670833\)](#)).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

#### 12.3.14.7 GID-2670831 [TIMESTAMP EXTENDED] LL-HH CONFIGURATION (SR0526.8.58)

If the checks are activated for the available limit ranges, the checks are performed in the following order:

1. LL-HH
2. L-H (defined with the **L-H configuration (SR0526.8.57)** process parameter ([\(GID-2670830\)](#))

Attribute	Type	Comment
Enabled	Flag	Controls if a check is performed. If so, ensure that the <b>LL limit</b> or <b>HH limit</b> attributes of the <b>Limit definition parameters</b> process parameter ( <a href="#">(GID-2670832)</a> ) are set. If they are not set, the validation will fail. Default setting: <b>No</b> .

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Attribute	Type	Comment
Risk assessment	Choice list	Defines the risk level of the exception and thus controls the related signature privilege. Available settings: <b>None</b> , <b>Low</b> , <b>Low (mandatory comment)</b> , <b>Medium</b> , <b>Medium (mandatory comment)</b> , <b>High</b> , <b>High (mandatory comment)</b> . Default setting: <b>High</b> .
Exception text	Text	Defines the exception description used during exception handling and within the batch record. Maximum length is 250 characters.

See also **Limit violation (SR0526.3.2.1)** system-triggered exception ([GID-2670833](#)).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

#### 12.3.14.8 GID-2670832 [TIMESTAMP EXTENDED] LIMIT DEFINITION PARAMETERS (SR0526.8.59)

The following rule applies to the attributes:

- LL limit < L limit < H limit < HH limit

Attribute	Type	Comment
Parameter for LL limit	String	Define the names of the lower limits parameters on the DCS. Maximum length is 200 characters.
Parameter for L limit	String	Define the names of the upper limits parameters on the DCS. Maximum length is 200 characters.
Parameter for H limit	String	Define the names of the lower limits parameters on the DCS. Maximum length is 200 characters.
Parameter for HH limit	String	Define the names of the upper limits parameters on the DCS. Maximum length is 200 characters.

See also **Limit violation (SR0526.3.2.1)** system-triggered exception ([GID-2670833](#)).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

## 12.4 Exceptions (SR0526.3+)

The phase supports user-defined, user-triggered ([GID-2668865](#)), system-triggered ([GID-2668864](#)), and post-completion exceptions ([GID-2668866](#)) and their configuration by means of process parameters ([GID-2667757](#))

User-defined exceptions cannot be configured by process parameters since they are provided by the framework and independent of phases.

### 12.4.1 System-triggered Exceptions (SR0526.3.2+)

A system-triggered exception is represented in a message dialog along with an **Exception** button, in the Exception Window as the read-only description of the exception, and in the batch report.

The following system-triggered exceptions are available.

#### 12.4.1.1 GID-2670833 LIMIT VIOLATION (SR0526.3.2.1)

If several checks fail during the execution of the **Get** action, the exceptions are combined and displayed in a single exception. The highest risk assessment of all related exceptions and its related signature privilege apply.

Representation of the exception:

- A violation of limits or expected values has occurred.
- List of up to 50 bundle parameters in the order of the bundle-specific process parameters:
  - **Boolean Value Bundle** (expected value violation):
 

Exception text:  
<Exception text>  
(taken from **Expected value configuration (SR0526.8.7)** process parameter ([GID-2670765](#))  
Parameter: <identifier> (<parameter description>  
(taken from the boolean-specific **Master (bundle identifier) (SR0526.8.6)** process parameter ([GID-2670761](#))  
Expected value <expected value>  
(taken from **Expected value definition (SR0526.8.8)** process parameter ([GID-2670766](#))  
Actual value: <actual value>
  - Example:  
Expected value violation confirmed.  
Parameter: HeatingPerformed (HeatingPerformed-10)  
Expected value: Yes  
Actual value: No

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- **Boolean Value (Extended) Bundle** (expected value violation):

Exception text:

<Exception text>

(taken from **Expected value configuration (SR0526.8.12)** process parameter ([GID-2671665](#)))

Parameter: <identifier> (<description parameter>)

(taken from the boolean-specific **Master (bundle identifier) (SR0526.8.11)** process parameter ([GID-2670768](#)))

Expected value <expected value>

(taken from **Expected value definition parameter (SR0526.8.13)** process parameter ([GID-2671666](#)))

Actual value: <actual value>

- **Duration Value Bundle** (limit violation):

Exception text:

<Exception text>

(taken from **L-H configuration (SR0526.8.17)** process parameter ([GID-2670777](#)) or **LL-HH configuration (SR0526.8.18)** process parameter ([GID-2670778](#)))

Parameter: <identifier> (<parameter description>)

(taken from the duration-specific **Master (bundle identifier) (SR0526.8.16)** process parameter ([GID-2670773](#)))

<Affected limit, L, LL, H, HH>: <limit value>

(taken from **Limit definition (SR0526.8.19)** process parameter ([GID-2670779](#)))

Actual value: <actual value>

- Example:

Limit violation confirmed.

Parameter: AgitatorSpeed (AgitatorSpeed-10)

LL limit: 300 min

Actual value: 200 min

- **Duration Value (Extended) Bundle** (limit violation):

Exception text:

<Exception text>

(taken from **L-H configuration (SR0526.8.23)** process parameter ([GID-2670785](#)) or **LL-HH configuration (SR0526.8.24)** process parameter ([GID-2670786](#)))

Parameter: <identifier> (<description parameter>)

(taken from the duration-specific **Master (bundle identifier) (SR0526.8.22)** process parameter ([GID-2670781](#)))

<Affected limit, L, LL, H, HH>: <limit value>

(taken from **Limit definition parameters (SR0526.8.25)** process parameter ([GID-2670787](#)))

Actual value: <actual value>

- **Numeric Value Bundle** (limit violation):

Exception text:

<Exception text>

(taken from **L-H configuration (SR0526.8.29)** process parameter ([GID-2670793](#)) or **LL-HH configuration (SR0526.8.30)** process parameter ([GID-2670794](#)))

Parameter: <identifier> (<parameter description>)

(taken from the numeric-specific **Master (bundle identifier) (SR0526.8.28)** process parameter ([GID-2670789](#)))

<Affected limit, L, LL, H, HH>: <limit value>

(taken from **Limit definition (SR0526.8.31)** process parameter ([GID-2670795](#)))

Actual value: <actual value>

- Example:

Limit violation confirmed.

Parameter: AgitatorSpeed (AgitatorSpeed-10)

LL limit: 300 rpm

Actual value: 200 rpm

- **Numeric Value (Extended) Bundle** (limit violation):

Exception text:

<Exception text>

(taken from **L-H configuration (SR0526.8.35)** process parameter ([GID-2670801](#)) or **LL-HH configuration (SR0526.8.36)** process parameter ([GID-2670802](#)))

Parameter: <identifier> (<description parameter>)

(taken from the numeric-specific **Master (bundle identifier) (SR0526.8.34)** process parameter ([GID-2670797](#)))

<Affected limit, L, LL, H, HH>: <limit value>

(taken from **Limit definition parameters (SR0526.8.37)** process parameter ([GID-2670803](#)))

Actual value: <actual value>

- **String Value Bundle** (expected value violation)::

Exception text:

<Exception text>

(taken from **Expected value configuration (SR0526.8.41)** process parameter ([GID-2670809](#)))

Parameter: <identifier> (<parameter description>)

(taken from the string-specific **Master (bundle identifier) (SR0526.8.40)** process parameter ([GID-2670805](#)))

Expected value: <expected value>

(taken from **Expected value definition (SR0526.8.42)** process parameter ([GID-2670810](#)))

Actual value: <actual value>

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- Example:  
Expected value violation confirmed.  
Parameter: VisualCheckResult (VisualCheckResult-10)  
Expected value: Dark blue  
Actual value: Light blue
- **String Value (Extended) Bundle** (expected value violation):  
Exception text:  
<Exception text>  
(taken from **Expected value configuration (SR0526.8.46)** process parameter ([GID-2670815](#)))  
Parameter: <identifier> (<description parameter>)  
(taken from the string-specific **Master (bundle identifier) (SR0526.8.45)** process parameter ([GID-2670811](#)))  
Expected value: <expected value>  
(taken from **Expected value definition parameter (SR0526.8.47)** process parameter ([GID-2670816](#)))  
Actual value: <actual value>
- **Timestamp Value Bundle** (limit violation):  
Exception text:  
<Exception text>  
(taken from **L-H configuration (SR0526.8.51)** process parameter ([GID-2670822](#)) or **LL-HH configuration (SR0526.8.52)** process parameter ([GID-2670823](#)))  
Parameter: <identifier> (<parameter description>)  
(taken from the timestamp-specific **Master (bundle identifier) (SR0526.8.50)** process parameter ([GID-2670818](#)))  
<Affected limit, L, LL, H, HH>: <limit value>  
(taken from **Limit definition (SR0526.8.53)** process parameter ([GID-2670824](#)))  
Actual value: <actual value>
- Example:  
Limit violation confirmed.  
Parameter: ProcessStart (ProcessStart-10)  
LL limit: 10/22/2018 12:49:09 PM CET  
Actual value: 10/22/2018 10:49:09 PM CET

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- **Timestamp Value (Extended) Bundle** (limit violation):
 

Exception text:  
<Exception text>  
(taken from **L-H configuration (SR0526.8.57)** process parameter ([GID-2670830](#)) or **LL-HH configuration (SR0526.8.58)** process parameter ([GID-2670831](#)))  
Parameter: <identifier> (<description parameter>)  
(taken from the timestamp-specific **Master (bundle identifier) (SR0526.8.56)** process parameter ([GID-2670826](#)))  
<Affected limit, L, LL, H, HH>: <limit value>  
(taken from **Limit definition parameters (SR0526.8.59)** process parameter ([GID-2670832](#)))  
Actual value: <actual value>
- Configuration violation:  
Exception text:  
Configuration error  
Parameter: <identifier>
  - Value of expected value parameter <value> not retrieved.
  - Value of HH Limit parameter <value> not retrieved.
  - Value of H Limit parameter <value> not retrieved.
  - Value of LL Limit parameter <value> not retrieved.
  - Value of L Limit parameter <value> not retrieved.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

#### 12.4.1.2 GID-2670834 LIMIT VIOLATION - LOGIC (SR0526.3.2.1.1)

- Trigger: Check has failed
- Postcondition: Exception is recorded

Step	#	Description
Operator accepts exceptional situation	10	Phase shows exception description to be signed.
Operator signs exception	20	Phase records the exception.

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Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

#### 12.4.1.3 GID-2670835 MULTIPLE SYSTEM-TRIGGERED EXCEPTIONS (SR0526.3.2.2)

In case multiple system-triggered exceptions occur, only one combined exception (system-triggered exception) is recorded including information about all exceptions. The highest risk assessment of all related exceptions and its related signature privilege apply.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

#### 12.4.2 User-triggered Exceptions (SR0526.3.1+)

A user-triggered exception is represented in the list of available user-triggered exceptions in the Exception Window, as the description of the exception, and in the batch report.

The following user-triggered exceptions are available.

##### 12.4.2.1 GID-2670836 OVERRIDE DCS PARAMETER VALUE (SR0526.3.1.1)

The **Override DCS parameter value** exception allows an operator to override the parameter value read from the DCS (except for the parameter description, expected value, or limits retrieved by parameters) or to confirm that parameter description, expected value, or limits retrieved by parameters were not returned by the DCS and thus are missing.

There is one exception per boolean value-, boolean value (extended)-, duration value-, duration value (extended)-, numeric value-, numeric value (extended)-, string value-, string value (extended)-, timestamp value-, and timestamp value (extended)-specific process parameter.

Parameters for which an error has been detected are displayed at the top of the list properties.

Representation during exception handling:

- Instruction:  
 <Parameter> (<parameter description/description parameter>)  
 (taken from the boolean-specific **Master (bundle identifier)** (SR0526.8.6) process parameter ([GID-2670761](#)),  
 taken from the boolean-specific **Master (bundle identifier)** (SR0526.8.11) process parameter ([GID-2670768](#)),  
 taken from the duration-specific **Master (bundle identifier)** (SR0526.8.16) process parameter ([GID-2670773](#)),  
 taken from the duration-specific **Master (bundle identifier)** (SR0526.8.22) process parameter ([GID-2670781](#))  
 taken from the numeric-specific **Master (bundle identifier)** (SR0526.8.28) process parameter ([GID-2670789](#)),

taken from the numeric-specific **Master (bundle identifier) (SR0526.8.34)** process parameter ([GID-2670797](#))

taken from the string-specific **Master (bundle identifier) (SR0526.8.40)** process parameter ([GID-2670805](#)),

taken from the string-specific **Master (bundle identifier) (SR0526.8.45)** process parameter ([GID-2670811](#))

taken from the timestamp-specific **Master (bundle identifier) (SR0526.8.50)** process parameter ([GID-2670818](#)), or

taken from the timestamp-specific **Master (bundle identifier) (SR0526.8.56)** process parameter ([GID-2670826](#))

Override recorded value:

Current value: <current value>

New value: <value>

**Confirm** button.

- Exception text:

<Exception text>

(taken from **Override DCS parameter value (SR0526.8.4)** process parameter ([GID-2670759](#)))

<Parameter> (<parameter description/description parameter>)

(taken from the boolean-specific **Master (bundle identifier) (SR0526.8.6)** process parameter ([GID-2670761](#)),

taken from the boolean-specific **Master (bundle identifier) (SR0526.8.11)** process parameter ([GID-2670768](#)),

taken from the duration-specific **Master (bundle identifier) (SR0526.8.16)** process parameter ([GID-2670773](#)),

taken from the duration-specific **Master (bundle identifier) (SR0526.8.22)** process parameter ([GID-2670781](#))

taken from the numeric-specific **Master (bundle identifier) (SR0526.8.28)** process parameter ([GID-2670789](#)),

taken from the numeric-specific **Master (bundle identifier) (SR0526.8.34)** process parameter ([GID-2670797](#))

taken from the string-specific **Master (bundle identifier) (SR0526.8.40)** process parameter ([GID-2670805](#)),

taken from the string-specific **Master (bundle identifier) (SR0526.8.45)** process parameter ([GID-2670811](#))

taken from the timestamp-specific **Master (bundle identifier) (SR0526.8.50)** process parameter ([GID-2670818](#)), or

taken from the timestamp-specific **Master (bundle identifier) (SR0526.8.56)** process parameter ([GID-2670826](#))

Old value: <old value>

New value: <new value>

In case of missing return values for parameter description, expected value, or limits:

Value of <parameter description, expected value, or limit> not retrieved.

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- Example:

Value overridden.

Target batch ID (Target batch ID-10)

Old value: BX40060

New value: BX40060

Value of description parameter DCS batch not retrieved.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

#### 12.4.2.2 GID-2670837 OVERRIDE DCS PARAMETER VALUE - LOGIC (SR0526.3.1.1.1)

- Trigger: Exception is selected
- Postcondition: A value is set

Step	#	Description
Operator triggers exception	10	Phase displays Exception Window.
	20	Operator enters/selects value.
Operator confirms exception	30	If the related check is enabled, phase checks the value against the settings of the bundle-specific process parameter: <ul style="list-style-type: none"> <li>▪ Boolean value and Boolean value (extended) bundles: <b>Expected value definition (SR0526.8.8)</b> process parameter (<a href="#">GID-2670766</a>) and <b>Expected value definition parameter (SR0526.8.13)</b> process parameter (<a href="#">GID-2671666</a>),</li> <li>▪ Duration value and Duration value (extended) bundles: <b>Limit definition (SR0526.8.19)</b> process parameter (<a href="#">GID-2670779</a>) and <b>Limit definition parameters (SR0526.8.25)</b> process parameter (<a href="#">GID-2670787</a>),</li> <li>▪ Numeric value and Numeric value (extended) bundles: <b>Limit definition (SR0526.8.31)</b> process parameter (<a href="#">GID-2670795</a>) and <b>Limit definition parameters (SR0526.8.37)</b> process parameter (<a href="#">GID-2670803</a>),</li> <li>▪ String value and String value (extended) bundles: <b>Expected value definition (SR0526.8.42)</b> process parameter (<a href="#">GID-2670810</a>) and <b>Expected value definition parameter (SR0526.8.47)</b> process parameter (<a href="#">GID-2670816</a>),</li> <li>▪ Timestamp value and Timestamp value (extended) bundles: <b>Limit definition (SR0526.8.53)</b> process parameter (<a href="#">GID-2670824</a>) and</li> </ul>

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Step	#	Description
		<b>Limit definition parameters (SR0526.8.59)</b> process parameter ( <a href="#">GID-2670832</a> )
	30.1	<p>If the expected value or a limit is violated, phase displays a corresponding message dialog with an <b>Exception</b> button, the exception text (taken from the bundle-specific process parameters), the parameter identifier, the affected expected value or limit, and the actual value.</p> <ul style="list-style-type: none"> <li>▪ <b>Boolean value and Boolean value (extended)</b> bundles: <b>Expected value configuration (SR0526.8.7)</b> process parameter (<a href="#">GID-2670765</a>) and <b>Expected value configuration (SR0526.8.12)</b> process parameter (<a href="#">GID-2671665</a>),</li> <li>▪ <b>Duration value and Duration value (extended)</b> bundles: <b>L-H configuration (SR0526.8.17)</b> process parameter (<a href="#">GID-2670777</a>) or <b>LL-HH configuration (SR0526.8.18)</b> process parameter (<a href="#">GID-2670778</a>) and <b>L-H configuration (SR0526.8.23)</b> process parameter (<a href="#">GID-2670785</a>) or <b>LL-HH configuration (SR0526.8.24)</b> process parameter (<a href="#">GID-2670786</a>),</li> <li>▪ <b>Numeric value and Numeric value (extended)</b> bundles: <b>L-H configuration (SR0526.8.29)</b> process parameter (<a href="#">GID-2670793</a>) or <b>LL-HH configuration (SR0526.8.30)</b> process parameter (<a href="#">GID-2670794</a>) and <b>L-H configuration (SR0526.8.35)</b> process parameter (<a href="#">GID-2670801</a>) or <b>LL-HH configuration (SR0526.8.36)</b> process parameter (<a href="#">GID-2670802</a>)</li> <li>▪ <b>String value and String value (extended)</b> bundles: <b>Expected value configuration (SR0526.8.41)</b> process parameter (<a href="#">GID-2670809</a>) and <b>Expected value configuration (SR0526.8.46)</b> process parameter (<a href="#">GID-2670815</a>),</li> <li>▪ <b>Timestamp value and Timestamp value (extended)</b> bundles: <b>L-H configuration (SR0526.8.51)</b> process parameter (<a href="#">GID-2670822</a>) or <b>LL-HH configuration (SR0526.8.52)</b> process parameter (<a href="#">GID-2670823</a>) and <b>L-H configuration (SR0526.8.57)</b> process parameter (<a href="#">GID-2670830</a>) or <b>LL-HH configuration (SR0526.8.58)</b> process parameter (<a href="#">GID-2670831</a>).</li> </ul>
Operator accepts exceptional situation	30.1.1	Phase displays only one combined exception (user-triggered exception), including both exception texts from the override-value-exception and from the violation of the expected value (see <b>Limit violation (SR0526.3.2.1)</b> system-triggered exception ( <a href="#">GID-2670833</a> )).
Operator cancels exceptional situation	30.1.2	Phase requires the operator to sign an <b>Exception canceled</b> exception and then allows the operator to return to the user-triggered exception view (Step 20).

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Step	#	Description
	30.2	If no expected value or limit is violated or no check applies, the override value-related exception is displayed.
	30.3	If the following issue occurs, phase displays an error message: <ul style="list-style-type: none"> <li>▪ Override value is missing, <b>No value overridden (SR0526.3.6.4)</b> error message (<a href="#">GID-2670841</a>).</li> </ul> Phase shows exception description to be signed according to <b>Override DCS parameter value (SR0526.8.4)</b> process parameter ( <a href="#">GID-2670759</a> ).
	30.4	For <b>Numeric value</b> and <b>Numeric value (extended)</b> bundles, if a value outside of the range is entered, the range violation-related error is displayed.
	30.5	If the above issue occurs, phase displays an error message: <ul style="list-style-type: none"> <li>▪ &lt;entered value&gt; is outside of the range of valid values. <b>Range violation error message (GID-3500023)</b>.</li> </ul>
Operator signs exception	40	Phase records the exception. Additionally, phase adds the exception marker to the value's cell in the <b>Active mode (SR0526.1.2)</b> layout ( <a href="#">GID-2670740</a> ).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

#### 12.4.3 Post-completion Exceptions

There are no post-completion exceptions available.

#### 12.5 Information Messages (SR0526.3.4+)

Information messages are represented in an information dialog containing a message type-specific icon, the information message, and an **OK** button.

The following information messages are available to inform the operator about how to proceed.

- Get DCS Parameters Phase (SR0526+)
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#### 12.5.1 *GID-2668867 Override value recorded (SR0526.3.4.1)*

UI text	Comment
<ul style="list-style-type: none"> <li>▪ Values have already been overridden manually.</li> <li>▪ &lt;list of parameters&gt;</li> </ul>	<ul style="list-style-type: none"> <li>▪ Message pack: PhaseDCSGetDCSParameters&lt;version&gt; Message ID: OverriddenValuesList_Info</li> <li>▪ Message pack: PhaseDCSGetDCSParameters&lt;version&gt; Message ID: Value_Info</li> </ul> <p>Potential error cause: <b>Get</b> button is used after the <b>Override DCS parameter value (SR0526.3.1.1)</b> user-triggered exception (<a href="#">GID-2670836</a>) has been signed.</p>

The **Details** button provides access to more specific technical information.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

#### 12.6 Questions

There are no questions available.

#### 12.7 Decisions

There are no decisions available.

#### 12.8 Error Messages (SR0526.3.6+)

Error messages are represented in an error message dialog containing a message type-specific icon, the error message, and an **OK** button.

The following error messages are available to inform the operator about error conditions.

##### 12.8.1 *Get DCS Parameter Value-specific Error Messages*

###### 12.8.1.1 **GID-2670838 NO GET RESULT ERROR (SR0526.3.6.1)**

UI text	Comment
Configuration error. Please record the values manually.	<p>Message pack: PhaseDCSGetDCSParameters&lt;version&gt; Message ID: BatchGetValuesConfigError_message</p> <p>Potential error cause: A required attribute of a process parameter is not configured correctly.</p>
The Get action was not successful.	<p>Message pack: PhaseDCSGetDCSParameters&lt;version&gt; Message ID: BatchGetValuesError_message</p>

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UI text	Comment
	<p>Potential error cause:</p> <ul style="list-style-type: none"> <li>▪ An error occurred while values were retrieved from the DCS.</li> <li>▪ A timeout occurred.</li> <li>▪ Not all values are available on the DCS.</li> <li>▪ Values could not be retrieved (null value was returned).</li> </ul>

The **Details** button provides access to more specific technical information.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

### 12.8.2 Phase Completion-specific Error Messages

#### 12.8.2.1 GID-2670839 RECORDED VALUES INCOMPLETE (SR0526.3.6.2)

UI text	Comment
Cannot confirm. Not all expected values have been recorded.	<p>Message pack: PhaseDCSGetDCSParameters&lt;version&gt; Message ID: CompletionError_HeaderMsg</p> <p>Potential error cause: The values of the defined parameters were not read successfully or overridden. Expected values are still missing.</p>

The **Details** button provides access to more specific technical information.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

### **12.8.3 User-triggered Exception-specific Error Messages**

#### **12.8.3.1 GID-2670840 INVALID DATA FORMAT ERROR (SR0526.3.6.3)**

UI text	Comment
The value must be a timestamp. Please correct your input.	Message pack: PhaseDCSGetDCSParameters<version> Message ID: OverrideDCSParameterDateTimeError_Error  Potential error cause: The entered text value cannot be converted to a timestamp value of the targeted timestamp data type.
The value must be a duration. Please correct your input.	Message pack: PhaseDCSGetDCSParameters<version> Message ID: OverrideDCSParameterDurationError_Error  Potential error cause: The entered text value cannot be converted to a duration value of the targeted duration data type.
The value must be a number. Please correct your input.	Message pack: PhaseDCSGetDCSParameters<version> Message ID: OverrideDCSParameterNumberError_Error  Potential error cause: The entered text value cannot be converted to a numeric value of the targeted numeric data type.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

#### **12.8.3.2 GID-2670841 NO VALUE OVERRIDDEN (SR0526.3.6.4)**

UI text	Comment
Select a new value.	Message pack: PhaseDCSGetDCSParameters<version> Message ID: OverrideBooleanValueNotSet_ErrorMsg  Potential error cause: No override value was selected before the user-triggered exception was confirmed.
Enter a new value.	Message pack: PhaseDCSGetDCSParameters<version> Message ID: OverrideDurationValueNotSet_ErrorMsg  Potential error cause: No override value was entered before the user-triggered exception was confirmed.
Enter a new value.	Message pack: PhaseDCSGetDCSParameters<version> Message ID: OverrideNumericValueNotSet_ErrorMsg

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UI text	Comment
	Potential error cause: No override value was entered before the user-triggered exception was confirmed.
Enter a new value.	Message pack: PhaseDCSGetDCSParameters<version> Message ID: OverrideStringValueNotSet_ErrorMsg  Potential error cause: No override value was entered before the user-triggered exception was confirmed.
Enter a new value.	Message pack: PhaseDCSGetDCSParameters<version> Message ID: OverrideDateTimeValueNotSet_ErrorMsg  Potential error cause: No override value was entered before the user-triggered exception was confirmed.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

#### 12.8.3.3 GID-3500023 RANGE VIOLATION ERROR

UI text	Comment
<entered value> is outside of the range of valid values. The value must not be lower than <lower limit> and higher than <upper limit>.	Message pack: PhaseDCSGetDCSParameters1101 Message ID: RangeViolation_ErrorMsg  Potential error cause: The entered value is outside the range of valid values.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

### 12.9 Output Variables (SR0526.9+)

The following output variables are available to reference the phase's output.

#### 12.9.1 Instance count (Framework capability)

- Data type: Long
- Usage: The output variable provides the count of the number of instances the phase has been processed, for example in a loop. The count is also increased when the phase is skipped from an operator's perspective, since the phase is still executed, but as a hidden phase.  
The count variable of a phase that has not been executed provides 0 as output value.

### **12.9.2 Start time (Framework capability)**

- Data type: Timestamp
- Usage: The output variable provides the start time of the phase.

### **12.9.3 Completion time (Framework capability)**

- Data type: Timestamp
- Usage: The output variable provides the completion time of the phase.

### **12.9.4 Identifier (Framework capability)**

- Data type: String
- Usage: The output variable provides the identifier of the phase.

### **12.9.5 GID-2668875 Retrieval successful (SR0526.9.1)**

- Data type: Boolean
- Values: true, false
- Usage: The output variable states if the get operation from the DCS was successful.
  - The value is true if all parameter values have been read successfully.
  - The value is false if at least one of the parameter values was not read from the DCS.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

### **12.9.6 Boolean Value Bundle**

#### **12.9.6.1 [BOOLEAN] BUNDLE OUTPUT VARIABLE (FRAMEWORK CAPABILITY)**

For all output variables of the same bundle, the output variable identifier is a concatenation of the bundle identifier and the output variable name.

This framework capability refers to **Bundle Output Variable (SR3146.9.7.4.2)** in "Functional Requirement Specification Recipe and Workflow Management" [A4] ([GID-2667776](#))

#### **12.9.6.2 GID-2670843 [BOOLEAN] VALUE (SR0526.9.2)**

- Data type: Boolean
- Usage: The output variable provides the value of the boolean parameter. The value is Null if N/A is the phase result.

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Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

#### 12.9.6.3 GID-2670844 [BOOLEAN] RETRIEVAL SUCCESSFUL (SR0526.9.3)

- Data type: Boolean
- Values: true, false
- Usage: The output variable states if the get operation from the DCS was successful.
  - The value is true if the parameter value of the boolean parameter has been read successfully.
  - The value is false if the parameter value of the boolean parameter was not read from the DCS.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

#### 12.9.7 Boolean Value (Extended) Bundle

##### 12.9.7.1 [BOOLEAN EXTENDED] BUNDLE OUTPUT VARIABLE (FRAMEWORK CAPABILITY)

For all output variables of the same bundle, the output variable identifier is a concatenation of the bundle identifier and the output variable name.

This framework capability refers to **Bundle Output Variable (SR3146.9.7.4.2)** in "Functional Requirement Specification Recipe and Workflow Management" [A4] ([GID-2667776](#))

##### 12.9.7.2 GID-2670846 [BOOLEAN EXTENDED] VALUE (SR0526.9.4)

- Data type: Boolean
- Usage: The output variable provides the value of the boolean parameter. The value is Null if N/A is the phase result.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

##### 12.9.7.3 GID-2670847 [BOOLEAN EXTENDED] RETRIEVAL SUCCESSFUL (SR0526.9.5)

- Data type: Boolean
- Values: true, false
- Usage: The output variable states if the get operation from the DCS was successful.

- The value is true if the parameter values of the boolean parameter have been read successfully.
- The value is false if a parameter value of the boolean parameter (value, description, expected value) was not read from the DCS.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

### 12.9.8 Duration Value Bundle

#### 12.9.8.1 [DURATION] BUNDLE OUTPUT VARIABLE (FRAMEWORK CAPABILITY)

For all output variables of the same bundle, the output variable identifier is a concatenation of the bundle identifier and the output variable name.

This framework capability refers to **Bundle Output Variable (SR3146.9.7.4.2)** in "Functional Requirement Specification Recipe and Workflow Management" [A4] ([GID-2667776](#))

#### 12.9.8.2 GID-2670849 [DURATION] VALUE (SR0526.9.6)

- Data type: Duration
- Usage: The output variable provides the value of the duration parameter. The value is Null if N/A is the phase result.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

#### 12.9.8.3 GID-2670850 [DURATION] RETRIEVAL SUCCESSFUL (SR0526.9.7)

- Data type: Boolean
- Values: true, false
- Usage: The output variable states if the get operation from the DCS was successful.
  - The value is true if the parameter value of the duration parameter has been read successfully.
  - The value is false if the parameter value of the duration parameter was not read from the DCS.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

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### **12.9.9 Duration Value (Extended) Bundle**

#### **12.9.9.1 [DURATION EXTENDED] BUNDLE OUTPUT VARIABLE (FRAMEWORK CAPABILITY)**

For all output variables of the same bundle, the output variable identifier is a concatenation of the bundle identifier and the output variable name.

This framework capability refers to **Bundle Output Variable (SR3146.9.7.4.2)** in "Functional Requirement Specification Recipe and Workflow Management" [A4] ([GID-2667776](#))

#### **12.9.9.2 GID-2670852 [DURATION EXTENDED] VALUE (SR0526.9.8)**

- Data type: Duration
- Usage: The output variable provides the value of the duration parameter. The value is Null if N/A is the phase result.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

#### **12.9.9.3 GID-2670853 [DURATION EXTENDED] RETRIEVAL SUCCESSFUL (SR0526.9.9)**

- Data type: Boolean
- Values: true, false
- Usage: The output variable states if the get operation from the DCS was successful.
  - The value is true if the parameter values of the duration parameter have been read successfully.
  - The value is false if a parameter value of the duration parameter (value, description, limit) was not read from the DCS.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

### **12.9.10 Numeric Value Bundle**

#### **12.9.10.1 [NUMERIC] BUNDLE OUTPUT VARIABLE (FRAMEWORK CAPABILITY)**

For all output variables of the same bundle, the output variable identifier is a concatenation of the bundle identifier and the output variable name.

This framework capability refers to **Bundle Output Variable (SR3146.9.7.4.2)** in "Functional Requirement Specification Recipe and Workflow Management" [A4] ([GID-2667776](#))

### 12.9.10.2 GID-2670855 [NUMERIC] VALUE (SR0526.9.10)

- Data type: BigDecimal
- Usage: The output variable provides the actual value of the numeric parameter as a **BigDecimal** value. The value is Null if N/A is the phase result.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

### 12.9.10.3 GID-2670856 [NUMERIC] RETRIEVAL SUCCESSFUL (SR0526.9.11)

- Data type: Boolean
- Values: true, false
- Usage: The output variable states if the get operation from the DCS was successful.
  - The value is true if the parameter value of the numeric parameter has been read successfully.
  - The value is false if the parameter value of the numeric parameter was not read from the DCS.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

## 12.9.11 Numeric Value (Extended) Bundle

### 12.9.11.1 [NUMERIC EXTENDED] BUNDLE OUTPUT VARIABLE (FRAMEWORK CAPABILITY)

For all output variables of the same bundle, the output variable identifier is a concatenation of the bundle identifier and the output variable name.

This framework capability refers to **Bundle Output Variable (SR3146.9.7.4.2)** in "Functional Requirement Specification Recipe and Workflow Management" [A4] ([GID-2667776](#))

### 12.9.11.2 GID-2670858 [NUMERIC EXTENDED] VALUE (SR0526.9.12)

- Data type: BigDecimal
- Usage: The output variable provides the actual value of the numeric parameter as a **BigDecimal** value. The value is Null if N/A is the phase result.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

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#### 12.9.11.3 GID-2670859 [NUMERIC EXTENDED] RETRIEVAL SUCCESSFUL (SR0526.9.13)

- Data type: Boolean
- Values: true, false
- Usage: The output variable states if the get operation from the DCS was successful.
  - The value is true if the parameter values of the numeric parameter have been read successfully.
  - The value is false if a parameter value of the numeric parameter (value, description, limit) was not read from the DCS.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

#### 12.9.12 String Value Bundle

##### 12.9.12.1 [STRING] BUNDLE OUTPUT VARIABLE (FRAMEWORK CAPABILITY)

For all output variables of the same bundle, the output variable identifier is a concatenation of the bundle identifier and the output variable name.

This framework capability refers to **Bundle Output Variable (SR3146.9.7.4.2)** in "Functional Requirement Specification Recipe and Workflow Management" [A4] ([GID-2667776](#))

##### 12.9.12.2 GID-2670861 [STRING] VALUE (SR0526.9.14)

- Data type: String
- Usage: The output variable provides the value of the string parameter. The value is Null if N/A is the phase result.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

##### 12.9.12.3 GID-2670862 [STRING] RETRIEVAL SUCCESSFUL (SR0526.9.15)

- Data type: Boolean
- Values: true, false
- Usage: The output variable states if the get operation from the DCS was successful.
  - The value is true if the parameter value of the string parameter has been read successfully.
  - The value is false if the parameter value of the string parameter was not read from the DCS.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

### 12.9.13 *String Value (Extended) Bundle*

#### 12.9.13.1 [STRING EXTENDED] BUNDLE OUTPUT VARIABLE (FRAMEWORK CAPABILITY)

For all output variables of the same bundle, the output variable identifier is a concatenation of the bundle identifier and the output variable name.

This framework capability refers to **Bundle Output Variable (SR3146.9.7.4.2)** in "Functional Requirement Specification Recipe and Workflow Management" [A4] ([GID-2667776](#))

#### 12.9.13.2 GID-2670864 [STRING EXTENDED] VALUE (SR0526.9.16)

- Data type: String
- Usage: The output variable provides the value of the string parameter. The value is Null if N/A is the phase result.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

#### 12.9.13.3 GID-2670865 [STRING EXTENDED] RETRIEVAL SUCCESSFUL (SR0526.9.17)

- Data type: Boolean
- Values: true, false
- Usage: The output variable states if the get operation from the DCS was successful.
  - The value is true if the parameter values of the string parameter have been read successfully.
  - The value is false if a parameter value of the string parameter (value, description, expected value) was not read from the DCS.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

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## 12.9.14 *Timestamp Value Bundle*

### 12.9.14.1 [TIMESTAMP] BUNDLE OUTPUT VARIABLE (FRAMEWORK CAPABILITY)

For all output variables of the same bundle, the output variable identifier is a concatenation of the bundle identifier and the output variable name.

This framework capability refers to **Bundle Output Variable (SR3146.9.7.4.2)** in "Functional Requirement Specification Recipe and Workflow Management" [A4] ([GID-2667776](#))

### 12.9.14.2 GID-2670867 [TIMESTAMP] VALUE (SR0526.9.18)

- Data type: Timestamp
- Usage: The output variable provides the value of the timestamp parameter. The value is Null if N/A is the phase result.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

### 12.9.14.3 GID-2670868 [TIMESTAMP] RETRIEVAL SUCCESSFUL (SR0526.9.19)

- Data type: Boolean
- Values: true, false
- Usage: The output variable states if the get operation from the DCS was successful.
  - The value is true if the parameter value of the timestamp parameter has been read successfully.
  - The value is false if the parameter value of the timestamp parameter was not read from the DCS.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

## 12.9.15 *Timestamp Value (Extended) Bundle*

### 12.9.15.1 [TIMESTAMP EXTENDED] BUNDLE OUTPUT VARIABLE (FRAMEWORK CAPABILITY)

For all output variables of the same bundle, the output variable identifier is a concatenation of the bundle identifier and the output variable name.

This framework capability refers to **Bundle Output Variable (SR3146.9.7.4.2)** in "Functional Requirement Specification Recipe and Workflow Management" [A4] ([GID-2667776](#))

### 12.9.15.2 GID-2670870 [TIMESTAMP EXTENDED] VALUE (SR0526.9.20)

- Data type: Timestamp
- Usage: The output variable provides the value of the timestamp parameter. The value is Null if N/A is the phase result.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

### 12.9.15.3 GID-2670871 [TIMESTAMP EXTENDED] RETRIEVAL SUCCESSFUL (SR0526.9.21)

- Data type: Boolean
- Values: true, false
- Usage: The output variable states if the get operation from the DCS was successful.
  - The value is true if the parameter values of the timestamp parameter have been read successfully.
  - The value is false if a parameter value of the timestamp parameter (value, description, limit) was not read from the DCS.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

## 12.10 Configuration Keys (SR0526.11+)

The following configuration keys are available to configure the phase's behavior.

### 12.10.1 GID-2668886 Message broker URL (SR0526.11.1)

- Phase/DCS/DCSMesssageBrokerURL
- **Type:** String
- **Value:** tcp://<hostname>:<port>
- **Description:** Specifies the URL of the messaging server used for DCS communication. Replace <hostname> with the name of the host to be used and <port> with the port number of the host to be used.  
If no value is set, the URL defined in the PharmaSuite **MessageBrokerURL** configuration key is used.
- **Evaluated:** When a DCS phase communicates with a DCS.
- **Range:** N/A

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Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

#### 12.10.2 *GID-2668887 Messaging timeout (SR0526.11.2)*

- Phase/DCS/DCSMessagingTimeout
- **Type:** Long
- Value: 2
- **Description:** The messaging timeout for DCS communication in seconds and the time how long a produced DCS message shall be retained by the messaging system after it has been dispatched. If no value is set, the timeout defined in the PharmaSuite **MessagingTimeout** configuration key is used (converted into seconds).
- **Evaluated:** When a DCS phase communicates with a DCS.
- **Range:** N/A

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

## 13 Set DCS Parameters Phase (SR0527+)

The **Set DCS parameters** phase allows an operator to set parameter values on a DCS.

An example use case is:

- GxP-relevant parameters for a process are maintained with the MES master recipe and needs to be transferred to the automation system (e.g., speed and duration for a blender).

Different phase modes enable the usage in various situations that can occur during processing:

- In the **Manual completion** mode, the operator manually triggers that the parameter values are set.
- In the **Automatic completion** mode, the phase sets the parameter values and is completed automatically without any operator interaction.

The DCS, batch, the parameters, and their values are stored in the batch record, thereby becoming available for documentation purposes in the sub-report and batch report ([GID-2668890](#)).

Anomalies that occur during processing are covered by the phase exception handling ([GID-2667769](#)) (e.g. re-send request).

After completion the phase displays the set parameters with their data in the Execution Window.

The Navigator displays the identifier of the updated batch.

Set the data on the DCS.

DCS name:	JavaDCSMock	Batch ID:	BX57_V399
Unit ID:	U207-22	Product ID:	D130-01
Recipe ID:	ID_SRTD-100	Data target:	Target 2
Module IDs:			
Parameters not set yet.	<span style="float: right;">Set </span>		
Parameter	Value		
Tablet Dimensions	9.0		
Tablet Form	Yes		
Status	OK		
Order Start	11/08/2018 04:43:30 AM IST		
Order Duration	7h		

Confirm 

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*Figure 12: Set DCS parameters during execution*

## 13.1 Layout

The phase provides individual layouts for its representation during execution ([\(GID-2668888\)](#) in the Navigator ([\(GID-2668889\)](#)), and in the sub-report ([\(GID-2668890\)](#)).

### 13.1.1 Representation during Execution (SR0527.1+)

The representation during execution depends on the phase mode.

#### 13.1.1.1 GID-2670872 PREVIEW MODE (SR0527.1.1)

1. <Instruction text>  
(taken from **Instruction (SR0527.8.1)** process parameter ([\(GID-2670888\)](#)))
2. DCS name: <logical name>  
Batch ID: <identifier>  
Unit ID: <identifier>  
Recipe ID: <identifier>  
Product ID: <identifier>  
Data target: <value>  
Module IDs: <identifiers>  
(taken from **DCS (SR0527.8.3)** process parameter ([\(GID-2670890\)](#)) and **Definition (SR0527.8.4)** process parameter ([\(GID-2670891\)](#)))
3. **Set** button (disabled).
4. Set action-specific information:
  - Parameters not set yet.
5. List of up to 50 bundle parameters in the order of the bundle-specific process parameters:
  - **Boolean Value Bundle:**
    - Parameter
    - Value
 (taken from the boolean value-specific **Master bundle identifier (SR0527.8.9)** process parameter ([\(GID-2670897\)](#)))
  - **Duration Value Bundle:**
    - Parameter
    - Value
 (taken from the duration value-specific **Master bundle identifier (SR0527.8.11)** process parameter ([\(GID-2670900\)](#)))

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▪ **Numeric Value Bundle:**

- Parameter Value  
(taken from the numeric value-specific **Master bundle identifier (SR0527.8.13)** process parameter ([GID-2670903](#)))

▪ **String Value Bundle:**

- Parameter Value  
(taken from the string value-specific **Master bundle identifier (SR0527.8.15)** process parameter ([GID-2670906](#)))

▪ **Timestamp Value Bundle:**

- Parameter Value  
(taken from the timestamp value-specific **Master bundle identifier (SR0527.8.17)** process parameter ([GID-2670909](#)))

6. **Confirm** button (disabled).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	Medium
MES-Compliance: 21 CFR Part 11 relevance	No

#### 13.1.1.2 GID-2670873 ACTIVE MODE (SR0527.1.2)

1. Instruction table panel and/or instruction link panel  
(only if an instruction table and/or instruction link is defined for the phase)
2. <Instruction text>  
(taken from **Instruction (SR0527.8.1)** process parameter ([GID-2670888](#)))
3. DCS name: <logical name>  
Batch ID: <identifier>  
Unit ID: <identifier>  
Recipe ID: <identifier>  
Product ID: <identifier>  
Data target: <value>  
Module IDs: <identifiers>  
(taken from **DCS (SR0527.8.3)** process parameter ([GID-2670890](#)) and **Definition (SR0527.8.4)** process parameter ([GID-2670891](#)))
4. **Set** button (disabled after a set request has been sent).

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5. Set action-specific information:

- Parameters not set yet.  
Initial message, parameter was overridden with the **Override bundle parameter (SR0527.3.1.3)** user-triggered exception ([GID-2670915](#)), or definition was overridden with the **Override definition (SR0527.3.1.4)** user-triggered exception ([GID-2670917](#)).
- Error when setting parameters.  
Parameters could not be set with the **Set** button.
- Error when re-setting parameters.  
Parameters could not be set with the **Re-send request (SR0527.3.1.1)** user-triggered exception ([GID-2670911](#))
- Sent at: <timestamp>

6. List of up to 50 bundle parameters in the order of the bundle-specific process parameters:

- **Boolean Value Bundle:**
  - Parameter  
Value  
(taken from the boolean value-specific **Master bundle identifier (SR0527.8.9)** process parameter ([GID-2670897](#)))
- **Duration Value Bundle:**
  - Parameter  
Value  
(taken from the duration value-specific **Master bundle identifier (SR0527.8.11)** process parameter ([GID-2670900](#)))
- **Numeric Value Bundle:**
  - Parameter  
Value  
(taken from the numeric value-specific **Master bundle identifier (SR0527.8.13)** process parameter ([GID-2670903](#)))
- **String Value Bundle:**
  - Parameter  
Value  
(taken from the string value-specific **Master bundle identifier (SR0527.8.15)** process parameter ([GID-2670906](#)))
- **Timestamp Value Bundle:**
  - Parameter  
Value  
(taken from the timestamp value-specific **Master bundle identifier (SR0527.8.17)** process parameter ([GID-2670909](#)))

7. **Confirm** button.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

#### 13.1.1.3 GID-2670874 COMPLETED MODE (SR0527.1.3)

1. Instruction table panel and/or instruction link panel  
(only if an instruction table and/or instruction link is defined for the phase)
2. <Instruction text>  
(taken from **Instruction (SR0527.8.1)** process parameter ([GID-2670888](#)))
3. DCS name: <logical name>  
Batch ID: <identifier>  
Unit ID: <identifier>  
Recipe ID: <identifier>  
Product ID: <identifier>  
Data target: <value>  
Module IDs: <identifiers>  
(taken from **DCS (SR0527.8.3)** process parameter ([GID-2670890](#)) and **Definition (SR0527.8.4)** process parameter ([GID-2670891](#)))
4. **Set** button (disabled).
5. Set action-specific information:
  - Sent at: <timestamp>
6. List of up to 50 bundle parameters in the order of the bundle-specific process parameters:
  - **Boolean Value Bundle:**
    - Parameter
    - Value

(taken from the boolean value-specific **Master bundle identifier (SR0527.8.9)** process parameter ([GID-2670897](#)))
  - **Duration Value Bundle:**
    - Parameter
    - Value

(taken from the duration value-specific **Master bundle identifier (SR0527.8.11)** process parameter ([GID-2670900](#)))

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- **Numeric Value Bundle:**
  - Parameter Value  
(taken from the numeric value-specific **Master bundle identifier (SR0527.8.13)** process parameter ([GID-2670903](#)))
- **String Value Bundle:**
  - Parameter Value  
(taken from the string value-specific **Master bundle identifier (SR0527.8.15)** process parameter ([GID-2670906](#)))
- **Timestamp Value Bundle:**
  - Parameter Value  
(taken from the timestamp value-specific **Master bundle identifier (SR0527.8.17)** process parameter ([GID-2670909](#)))

7. **Confirm** button (completed).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

### 13.1.2 Representation in Navigator (SR0527.4+)

The Navigator provides the following details:

#### 13.1.2.1 PHASE COLUMN (FRAMEWORK CAPABILITY)

- <Phase name>
  - Example:  
Set values on DCS

#### 13.1.2.2 GID-2670876 INFORMATION COLUMN (SR0527.4.1)

- <Batch identifier>
  - Example: BX2859\_V15900

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	Medium
MES-Compliance: 21 CFR Part 11 relevance	No

### 13.1.2.3 ACTION COLUMN

- There are no phase-specific actions available.

### 13.1.3 Representation in Sub-report (SR0527.5+)

The sub-report contains the following information:

#### 13.1.3.1 COMMON SUB-REPORT ELEMENTS (FRAMEWORK CAPABILITY)

- <Start time>
- <Completion time>
- <Unit procedure> / <operation> / <phase>
- <Work center> / <station> / <device> - <phase completion user>

#### 13.1.3.2 GID-2670879 SUB-REPORT ELEMENTS (SR0527.5.1)

- Instruction table panel and/or instruction link panel  
(only if an instruction table and/or instruction link is defined for the phase)
- Instruction text
- DCS name: <logical name>  
Batch ID: <identifier>  
Unit ID: <identifier>  
Recipe ID: <identifier>  
Product ID: <identifier>  
Data target: <value>  
Module IDs: <identifiers>
- Set action-specific information:
  - Sent at: <timestamp>
- Table of values (boolean, duration, numeric, string, timestamp) that have been set on the DCS (in the order of the process parameters).
  - Parameter
  - Value

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

## 13.2 Business Logic (SR0527.2+)

- The phase implements the following business logic.

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### 13.2.1 Phase Mode

Business logic related to phase modes.

#### 13.2.1.1 GID-2670880 MANUAL COMPLETION MODE (SR0527.2.1)

- Function: **Manual completion** mode of phase
- Type: Phase mode
- Trigger: Phase becomes active
- Postcondition: Phase is active

Step	#	Description
Phase activation	10	Phase displays its user interface according to the <b>Active mode</b> (SR0527.1.2) layout ( <a href="#">GID-2670873</a> ).
Operator taps Set button	20	Phase sets the parameter values on the DCS, see <b>Set parameter values</b> (SR0527.2.3) function ( <a href="#">GID-2670882</a> ).
Phase completion	30	See <b>Confirm phase</b> (SR0527.2.4) function ( <a href="#">GID-2670883</a> ).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

#### 13.2.1.2 GID-2670881 AUTOMATIC COMPLETION MODE (SR0527.2.2)

- Function: **Automatic completion** mode of phase
- Type: Phase mode
- Trigger: Phase becomes active
- Postcondition: Phase is active

Step	#	Description
Phase activation	10	Phase displays its user interface according to the <b>Active mode</b> (SR0527.1.2) layout ( <a href="#">GID-2670873</a> ).
Phase sets parameter values	20	See <b>Set parameter values</b> (SR0527.2.3) function ( <a href="#">GID-2670882</a> ). <ul style="list-style-type: none"> <li>▪ If no error has occurred, continue with the <b>Confirm phase</b> (SR0527.2.4) function (<a href="#">GID-2670883</a>).</li> <li>▪ If an error has occurred, phase must be completed manually. See <b>Manual completion</b> (SR0527.2.1) mode (<a href="#">GID-2670880</a>).</li> </ul>

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

### 13.2.2 Main Path

Business logic related to the main path:

#### 13.2.2.1 GID-2670882 SET PARAMETER VALUES (SR0527.2.3)

- Function: Request to set parameter values
- Type: Main path
- Trigger: Operator sets parameter values or **Automatic completion (SR0527.2.2)** mode ([GID-2670881](#)) is active
- Postcondition: Phase is active

Step	#	Description
Phase sets parameter values	10	Phase sets the parameter values on the DCS and disables the <b>Set</b> button.
	20.1	If an error has occurred, phase displays the <b>Set parameter error (SR0527.3.6.1)</b> error message ( <a href="#">GID-2670919</a> ). Continue with the <b>Re-send request (SR0527.3.1.1)</b> user-triggered exception ( <a href="#">GID-2670911</a> ), the <b>Override bundle parameter (SR0527.3.1.3)</b> user-triggered exception ( <a href="#">GID-2670915</a> ), the <b>Override definition (SR0527.3.1.4)</b> user-triggered exception ( <a href="#">GID-2670917</a> ), or the <b>Set DCS parameters manually (SR0527.3.1.2)</b> user-triggered exception ( <a href="#">GID-2670913</a> ). Phase can be completed with the <b>Confirm phase (SR0527.2.4)</b> function ( <a href="#">GID-2430815</a> ).
	20.2	If no error has occurred, continue with the <b>Confirm phase (SR0527.2.4)</b> function ( <a href="#">GID-2670883</a> ).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

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### 13.2.2.2 GID-2670883 CONFIRM PHASE (SR0527.2.4)

- Function: Completion of phase
- Type: Main path
- Trigger: Operator confirms phase or **Automatic completion (SR0527.2.2)** mode ([GID-2670881](#)) is active
- Postcondition: Phase is completed

Step	#	Description
In Manual completion (SR0527.2.1) mode ( <a href="#">GID-2670880</a> ): Operator confirms phase	10	Operator confirms that the parameters were set on the DCS.
Phase performs completion checks	20	If the parameters were not set and the <b>Set DCS parameters manually (SR0527.3.1.2)</b> user-triggered exception ( <a href="#">GID-2670913</a> ) was not added or the <b>Override bundle parameters (SR0527.3.1.3)</b> user-triggered exception ( <a href="#">GID-2670915</a> ) or the <b>Override definition (SR0527.3.1.4)</b> user-triggered exception ( <a href="#">GID-2670917</a> ) were added afterwards, phase displays the <b>No parameters set (SR0527.3.6.2)</b> error message ( <a href="#">GID-2670920</a> ). The phase can only be completed, when the parameters have been set.
Phase completion	30	Phase is completed.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

- Set DCS Parameters Phase (SR0527+)

## 13.3 Process Parameters (SR0527.8+)

The following process parameters define the behavior of the phase.

### 13.3.1 Instruction Table-specific Parameters

#### 13.3.1.1 INSTRUCTION TABLE DEFINITION (FRAMEWORK CAPABILITY)

Attribute	Type	Comment
Table layout	Choice list	Defines the layout of the instruction table holding the instruction texts. Available settings: <b>1 column</b> , <b>2 columns</b> , <b>3 columns</b> , <b>4 columns</b> , <b>5 columns</b> . Default setting: <b>1 column</b> .
First column narrow	Boolean	Defines if the first column of the table shall be narrow.
Show all borders	Boolean	Defines if the borders of the table shall be visible.

#### 13.3.1.2 INSTRUCTION TABLE TEXT (FRAMEWORK CAPABILITY)

Attribute	Type	Comment
Column 1	HTML text	Instruction text to be displayed in a column.
Column 2	HTML text	<b>Restriction:</b> Maximum length is 2000 characters (including HTML tags).
Column 3	HTML text	
Column 4	HTML text	
Column 5	HTML text	

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### **13.3.2 Instruction Link-specific Parameters**

#### **13.3.2.1 INSTRUCTION TEXT WITH LINKS (FRAMEWORK CAPABILITY)**

Attribute	Type	Comment
Instruction text	HTML text	<p>Instruction text to be displayed.</p> <p>For any text enclosed in curly brackets you can define a hyperlink with the <b>Instruction link definition</b> process parameter (<a href="#">GID-2670887</a>).</p> <p>Example: Refer to {SOP1270} for guidance.</p> <p>Maximum length is 2000 characters (including HTML tags).</p>

#### **13.3.2.2 INSTRUCTION LINK DEFINITION (FRAMEWORK CAPABILITY)**

Attribute	Type	Comment
Link text	Text	<p>Text to be used as link.</p> <p>For any text enclosed in curly brackets within the instruction text you can define a link with the <b>Link URL</b> attribute.</p> <p>Including the brackets in the link text is optional.</p> <p>Maximum length is 80 characters.</p>
Link URL	Text	<p>URL of the file to be displayed. The link opens the external application assigned to the file type by the operating system.</p> <p>Maximum length is 256 characters.</p>

- Set DCS Parameters Phase (SR0527+)

### 13.3.3 Basic Parameters

#### 13.3.3.1 GID-2670888 INSTRUCTION (SR0527.8.1)

Attribute	Type	Comment
Text	HTML text	Instruction text to be displayed. <b>Restriction:</b> Maximum length is 4000 characters (including HTML tags).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

#### 13.3.3.2 GID-2670889 MODE (SR0527.8.2)

Attribute	Type	Comment
Mode	Choice list	Defines the processing mode. <b>Manual completion</b> (default): Operator confirms the phase. <b>Automatic completion</b> : Phase is automatically completed after the parameter values have been set successfully on the DCS.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

#### 13.3.3.3 GID-2670890 DCS (SR0527.8.3)

Attribute	Type	Comment
Name	String	Logical name of the DCS to be used. The available entries correspond to the entries in the <b>DCSNames</b> list. Default setting: First entry in the list. Maximum length is 255 characters.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

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#### 13.3.3.4 GID-2670891 DEFINITION (SR0527.8.4)

Attribute	Type	Comment
Batch ID	String	Optional parameter to define the identifier of the batch whose parameter values will be set on the DCS. Maximum length is 250 characters.
Unit ID	String	Optional parameter to define the identifier of the unit to be used. Maximum length is 250 characters.
Module IDs	Text (structured)	Optional parameter to define the list of equipment module IDs and control module IDs. Maximum length is 2000 characters.
Product ID	String	Optional parameter to define the identifier of the product. Maximum length is 250 characters.
Recipe ID	String	Optional parameter to define the identifier of the recipe. Maximum length is 250 characters.
Data target	Choice list	Optional parameter to define how the message is processed in the Manufacturing Service Bus (MSB) (e.g., SMAC, ULDL, RMS). Maximum length is 250 characters. The available entries correspond to the entries in the <b>DCSDataTarget</b> list.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

- Set DCS Parameters Phase (SR0527+)

### 13.3.4 Configuration of User-triggered Exceptions

#### 13.3.4.1 GID-2670892 RE-SEND REQUEST (SR0527.8.5)

Attribute	Type	Comment
Risk assessment	Choice list	Defines the risk level of the exception and thus controls the related signature privilege. Available settings: <b>None</b> , <b>Low</b> , <b>Low (mandatory comment)</b> , <b>Medium</b> , <b>Medium (mandatory comment)</b> , <b>High</b> , <b>High (mandatory comment)</b> . Default setting: <b>High</b> , defined by the <b>DefaultRiskClassForPhaseProcessParameter</b> configuration key.
Exception text	Text	Defines the exception description used during exception handling and within the batch record. Maximum length is 256 characters.

See also Re-send request (SR0527.3.1.1) user-triggered exception ([GID-2670911](#)).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

#### 13.3.4.2 GID-2670893 SET DCS PARAMETERS MANUALLY (SR0527.8.6)

Attribute	Type	Comment
Risk assessment	Choice list	Defines the risk level of the exception and thus controls the related signature privilege. Available settings: <b>None</b> , <b>Low</b> , <b>Low (mandatory comment)</b> , <b>Medium</b> , <b>Medium (mandatory comment)</b> , <b>High</b> , <b>High (mandatory comment)</b> . Default setting: <b>High</b> , defined by the <b>DefaultRiskClassForPhaseProcessParameter</b> configuration key.
Exception text	Text	Defines the exception description used during exception handling and within the batch record. Maximum length is 256 characters.

See also Set DCS parameters manually (SR0527.3.1.2) user-triggered exception ([GID-2670913](#))

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Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

#### 13.3.4.3 GID-2670894 OVERRIDE BUNDLE PARAMETER (SR0527.8.7)

Attribute	Type	Comment
Risk assessment	Choice list	<p>Defines the risk level of the exception and thus controls the related signature privilege.</p> <p>Available settings: <b>None</b>, <b>Low</b>, <b>Low (mandatory comment)</b>, <b>Medium</b>, <b>Medium (mandatory comment)</b>, <b>High</b>, <b>High (mandatory comment)</b>.</p> <p>Default setting: <b>High</b>, defined by the <b>DefaultRiskClassForPhaseProcessParameter</b> configuration key.</p>
Exception text	Text	<p>Defines the exception description used during exception handling and within the batch record.</p> <p>Maximum length is 256 characters.</p>

See also **Override bundle parameter (SR0527.3.1.3)** user-triggered exception ([GID-2670915](#)).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

#### 13.3.4.4 GID-2670895 OVERRIDE DEFINITION (SR0527.8.8)

Attribute	Type	Comment
Risk assessment	Choice list	Defines the risk level of the exception and thus controls the related signature privilege. Available settings: <b>None</b> , <b>Low</b> , <b>Low (mandatory comment)</b> , <b>Medium</b> , <b>Medium (mandatory comment)</b> , <b>High</b> , <b>High (mandatory comment)</b> . Default setting: <b>High</b> , defined by the <b>DefaultRiskClassForPhaseProcessParameter</b> configuration key.
Exception text	Text	Defines the exception description used during exception handling and within the batch record. Maximum length is 256 characters.

See also **Override definition (SR0527.3.1.4)** user-triggered exception ([GID-2670917](#)).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

#### 13.3.5 Boolean Value Bundle

##### 13.3.5.1 [BOOLEAN] BUNDLE PROCESS PARAMETERS (FRAMEWORK CAPABILITY)

For the master process parameter of a bundle, its internal identifier is populated from the bundle identifier.

For all other process parameters of the bundle, their internal identifier is a concatenation of the bundle identifier and the process parameter name.

This framework capability refers to **Bundle Process Parameters (SR3146.9.7.4.1)** in "Functional Requirement Specification Recipe and Workflow Management" [A4] ([GID-2667776](#))

##### 13.3.5.2 GID-2670897 [BOOLEAN] MASTER (BUNDLE IDENTIFIER) (SR0527.8.9)

Attribute	Type	Comment
Parameter	String	Defines the identifier of the parameter to be used. Maximum length is 200 characters.
Value	Boolean	Defines the value of the parameter.

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Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

### 13.3.5.3 GID-2670898 [BOOLEAN] CATEGORY (SR0527.8.10)

Attribute	Type	Comment
Category	Choice list	Defines the category of the bundle. Available settings: ---, P1, P2, P3, P4.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

### 13.3.6 Duration Value Bundle

#### 13.3.6.1 [DURATION] BUNDLE PROCESS PARAMETERS (FRAMEWORK CAPABILITY)

For the master process parameter of a bundle, its internal identifier is populated from the bundle identifier.

For all other process parameters of the bundle, their internal identifier is a concatenation of the bundle identifier and the process parameter name.

This framework capability refers to **Bundle Process Parameters (SR3146.9.7.4.1)** in "Functional Requirement Specification Recipe and Workflow Management" [A4] ([GID-2667776](#))

#### 13.3.6.2 GID-2670900 [DURATION] MASTER (BUNDLE IDENTIFIER) (SR0527.8.11)

Attribute	Type	Comment
Parameter	String	Defines the identifier of the parameter to be used. Maximum length is 200 characters.
Value	Duration	Defines the value of the parameter.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

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### 13.3.6.3 GID-2670901 [DURATION] CATEGORY (SR0527.8.12)

Attribute	Type	Comment
Category	Choice list	Defines the category of the bundle. Available settings: ---, P1, P2, P3, P4.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

### 13.3.7 Numeric Value Bundle

#### 13.3.7.1 [NUMERIC] BUNDLE PROCESS PARAMETERS (FRAMEWORK CAPABILITY)

For the master process parameter of a bundle, its internal identifier is populated from the bundle identifier.

For all other process parameters of the bundle, their internal identifier is a concatenation of the bundle identifier and the process parameter name.

This framework capability refers to **Bundle Process Parameters (SR3146.9.7.4.1)** in "Functional Requirement Specification Recipe and Workflow Management" [A4] [\(GID-2667776\)](#)

#### 13.3.7.2 GID-2670903 [NUMERIC] MASTER (BUNDLE IDENTIFIER) (SR0527.8.13)

Attribute	Type	Comment
Parameter	String	Defines the identifier of the parameter to be used. Maximum length is 200 characters.
Value	BigDecimal	Defines the value of the parameter.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

#### 13.3.7.3 GID-2670904 [NUMERIC] CATEGORY (SR0527.8.14)

Attribute	Type	Comment
Category	Choice list	Defines the category of the bundle. Available settings: ---, P1, P2, P3, P4.

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Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

### 13.3.8 String Value Bundle

#### 13.3.8.1 [STRING] BUNDLE PROCESS PARAMETERS (FRAMEWORK CAPABILITY)

For the master process parameter of a bundle, its internal identifier is populated from the bundle identifier.

For all other process parameters of the bundle, their internal identifier is a concatenation of the bundle identifier and the process parameter name.

This framework capability refers to **Bundle Process Parameters (SR3146.9.7.4.1)** in "Functional Requirement Specification Recipe and Workflow Management" [A4] ([GID-2667776](#))

#### 13.3.8.2 GID-2670906 [STRING] MASTER (BUNDLE IDENTIFIER) (SR0527.8.15)

Attribute	Type	Comment
Parameter	String	Defines the identifier of the parameter to be used. Maximum length is 200 characters.
Value	String	Defines the value of the parameter. Maximum length is 2000 characters.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

#### 13.3.8.3 GID-2670907 [STRING] CATEGORY (SR0527.8.16)

Attribute	Type	Comment
Category	Choice list	Defines the category of the bundle. Available settings: ---, P1, P2, P3, P4.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

- Set DCS Parameters Phase (SR0527+)

### 13.3.9 *Timestamp Value Bundle*

#### 13.3.9.1 [TIMESTAMP] BUNDLE PROCESS PARAMETERS (FRAMEWORK CAPABILITY)

For the master process parameter of a bundle, its internal identifier is populated from the bundle identifier.

For all other process parameters of the bundle, their internal identifier is a concatenation of the bundle identifier and the process parameter name.

This framework capability refers to **Bundle Process Parameters (SR3146.9.7.4.1)** in "Functional Requirement Specification Recipe and Workflow Management" [A4] ([GID-2667776](#))

#### 13.3.9.2 GID-2670909 [TIMESTAMP] MASTER (BUNDLE IDENTIFIER) (SR0527.8.17)

Attribute	Type	Comment
Parameter	String	Defines the identifier of the parameter to be used. Maximum length is 200 characters.
Value	Timestamp	Defines the value of the parameter.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

#### 13.3.9.3 GID-2670910 [TIMESTAMP] CATEGORY (SR0527.8.18)

Attribute	Type	Comment
Category	Choice list	Defines the category of the bundle. Available settings: ---, P1, P2, P3, P4.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

### 13.4 Exceptions (SR0527.3+)

The phase supports user-defined, user-triggered ([GID-2669162](#)), system-triggered ([GID-2669161](#)), and post-completion exceptions ([GID-2669163](#)) and their configuration by means of process parameters ([GID-2667768](#)).

User-defined exceptions cannot be configured by process parameters since they are provided by the framework and independent of phases.

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### **13.4.1 System-triggered Exceptions**

There are no system-triggered exceptions available.

### **13.4.2 User-triggered Exceptions (SR0527.3.1+)**

A user-triggered exception is represented in the list of available user-triggered exceptions in the Exception Window, as the description of the exception, and in the batch report.

The following user-triggered exceptions are available.

#### **13.4.2.1 GID-2670911 RE-SEND REQUEST (SR0527.3.1.1)**

The **Re-send request** exception allows an operator to re-send the request to set the DCS parameter values to the DCS.

With the exception, the phase overrides the recently set parameter values, if available.

Representation of the exception:

- Instruction:  
Send parameters to the DCS.  
**Confirm** button.
- Exception text:  
<Exception text>  
(taken from **Re-send request (SR0527.8.5)** process parameter ([GID-2670892](#)))  
Batch ID: <value>
  - Example:  
Setting of parameters repeated.  
Batch ID: BX2859\_V15900

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

#### **13.4.2.2 GID-2670912 RE-SEND REQUEST - LOGIC (SR0527.3.1.1.1)**

- Trigger: Exception is selected
- Postcondition: DCS parameter values are set on the DCS

Step	#	Description
Operator confirms and signs exception	10	Phase records the exception and sends a request to set the DCS parameter values to the DCS.

Step	#	Description
Phase receives feedback from the DCS	20	<p>Phase adds a comment with the set result</p> <ul style="list-style-type: none"> <li>▪ Sent at &lt;timestamp&gt;</li> <li>▪ Setting of parameters failed</li> </ul> <p>to the exception, updates set parameters-specific information in the <b>Active mode (SR0527.1.2)</b> layout (<a href="#">GID-2670873</a>), and disables the <b>Set</b> button in the <b>Active mode (SR0527.1.2)</b> layout (<a href="#">GID-2670873</a>). If setting of the parameter values fails, the phase cannot be completed (see <b>Confirm phase (SR0527.2.4)</b> function (<a href="#">GID-2670883</a>)).</p>

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

#### 13.4.2.3 GID-2670913 SET DCS PARAMETERS MANUALLY (SR0527.3.1.2)

The **Set DCS parameters manually** exception allows an operator to complete the phase in case the parameters could not be set successfully with the phase on the DCS. With the exception, the operator confirms that all parameter values were set manually on the DCS.

Representation of the exception:

- Instruction:  
Set the DCS parameters manually.  
**Confirm** button.
- Exception text:  
<Exception text>  
(taken from **Set DCS parameters manually (SR0527.8.6)** process parameter ([GID-2670893](#)))
  - Example:  
Parameters set manually.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

#### 13.4.2.4 GID-2670914 SET DCS PARAMETERS MANUALLY - LOGIC (SR0527.3.1.2.1)

- Trigger: Exception is selected
- Postcondition: Phase can be completed without setting the parameters on the DCS.

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Step	#	Description
Operator confirms and signs exception	10	Phase records the exception and disables the <b>Set</b> button in the <b>Active mode (SR0527.1.2)</b> layout ( <a href="#">GID-2670873</a> ).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

#### 13.4.2.5 GID-2670915 OVERRIDE BUNDLE PARAMETER (SR0527.3.1.3)

The **Override bundle parameter** exception allows an operator to override the parameter value set on the DCS of a bundle-specific process parameter defined in the master recipe/workflow.

There is one exception per boolean value-, duration value-, numeric value-, string value-, and timestamp value-specific process parameter.

Representation during exception handling:

- Instruction:  
`<Parameter>`  
(taken from the boolean-specific **Master (bundle identifier)** (SR0527.8.9) process parameter ([GID-2670897](#)),  
taken from the duration-specific **Master (bundle identifier)** (SR0527.8.11) process parameter ([GID-2670900](#))  
taken from the numeric-specific **Master (bundle identifier)** (SR0527.8.13) process parameter ([GID-2670903](#)),  
taken from the string-specific **Master (bundle identifier)** (SR0527.8.15) process parameter ([GID-2670906](#)),  
taken from the timestamp-specific **Master (bundle identifier)** (SR0527.8.17) process parameter ([GID-2670909](#)))  
Override the defined value:  
Current value `<value>`  
New value `<value>`  
**Confirm** button.
- Exception text:  
`<Exception text>`  
(taken from **Override bundle parameter** (SR0527.8.7) process parameter ([GID-2670894](#)))  
`<Parameter>`  
(taken from the boolean-specific **Master (bundle identifier)** (SR0527.8.9) process parameter ([GID-2670897](#)),  
taken from the duration-specific **Master (bundle identifier)** (SR0527.8.11) process parameter ([GID-2670900](#))  
taken from the numeric-specific **Master (bundle identifier)** (SR0527.8.13) process parameter

- Set DCS Parameters Phase (SR0527+)

[\(GID-2670903\)](#),

taken from the string-specific **Master (bundle identifier) (SR0527.8.15)** process parameter [\(GID-2670906\)](#),

taken from the timestamp-specific **Master (bundle identifier) (SR0527.8.17)** process parameter [\(GID-2670909\)](#))

- Example:

Parameter overridden.

Table size

Old value: 7.8 mm

New value: 7.9 mm

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

#### 13.4.2.6 GID-2670916 OVERRIDE BUNDLE PARAMETER - LOGIC (SR0527.3.1.3.1)

- Trigger: Exception is selected
- Postcondition: Value of bundle parameter is overridden

Step	#	Description
Operator triggers exception	10	Phase displays Exception Window.
	20	Operator enters value.
Operator confirms exception	30	If the following issue occurs, phase displays an error message: <ul style="list-style-type: none"> <li>▪ Override value is missing, <b>No value overridden (SR0527.3.6.4)</b> error message <a href="#">(GID-2670922)</a>.</li> </ul> Phase shows exception description to be signed according to <b>Override bundle parameter (SR0527.8.7)</b> process parameter <a href="#">(GID-2670894)</a> .
Operator signs exception	40	Phase records the exception. Additionally, phase adds the exception marker to the value's cell in the <b>Active mode (SR0527.1.2)</b> layout <a href="#">(GID-2670873)</a> .
Operator interaction	50	Operator taps <b>Set</b> button in the <b>Active mode (SR0527.1.2)</b> layout <a href="#">(GID-2670873)</a> or triggers the <b>Re-send request (SR0527.3.1.1)</b> user-triggered exception <a href="#">(GID-2670911)</a> to set the DCS parameter values on the DCS with the new values.

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Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

#### 13.4.2.7 GID-2670917 OVERRIDE DEFINITION (SR0527.3.1.4)

The **Override definition** exception allows an operator to override the DCS parameters defined in the master recipe/workflow.

Representation of the exception:

- Instruction:

Override a definition parameter.

Batch ID:

Current value <value>

New value <value>

Unit ID:

Current value <value>

New value <value>

Recipe ID:

Current value <value>

New value <value>

Product ID:

Current value <value>

New value <value>

Data target:

Current value <value>

New value <value>

Module IDs:

Current value <value>

New value <value>

**Confirm** button.

- Exception text:

<Exception text>

(taken from **Override definition (SR0527.8.8)** process parameter ([GID-2670895](#)))

Batch ID:

Old value: <old value>

New value: <new value>

Unit ID:

Old value: <old value>

New value: <new value>

Recipe ID:

Old value: <old value>

New value: <new value>

Product ID:

Old value: <old value>  
 New value: <new value>  
 Data target:  
 Old value: <old value>  
 New value: <new value>  
 Module IDs:  
 Old value: <old value>  
 New value: <new value>

- Example:  
 Parameter overridden.  
 Batch ID:  
 Old value: BX2859\_V15901  
 New value: BX2859\_V15900  
 Recipe ID:  
 Old value: ID\_SRTD\_002  
 New value: ID\_SRTD\_001

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

#### 13.4.2.8 GID-2670918 OVERRIDE DEFINITION - LOGIC (SR0527.3.1.4.1)

- Trigger: Exception is selected
- Postcondition: Value of DCS parameter is overridden

Step	#	Description
Operator triggers exception	10	Phase displays Exception Window.
	20	Operator enters value.
Operator confirms exception	30	If the following issue occurs, phase displays an error message: <ul style="list-style-type: none"> <li>▪ Override value is missing, <b>No value overridden (SR0527.3.6.4)</b> error message (<a href="#">GID-2670922</a>).</li> </ul> Phase shows exception description to be signed according to <b>Override definition (SR0527.8.8)</b> process parameter ( <a href="#">GID-2670895</a> ).

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Step	#	Description
		For numeric-type bundle parameter, if a value outside of the range is entered, phase displays an error message: <ul style="list-style-type: none"> <li>▪ &lt;entered value&gt; is outside of the range of valid values. <b>Range violation error</b> message link.</li> </ul>
Operator signs exception	40	Phase records the exception.
Operator interaction	50	Operator taps <b>Set</b> button in the <b>Active mode (SR0527.1.2)</b> layout ( <a href="#">GID-2670873</a> ) or triggers the <b>Re-send request (SR0527.3.1.1)</b> user-triggered exception ( <a href="#">GID-2670911</a> ) to set the DCS parameter values on the DCS with the new values.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

#### 13.4.3 Post-completion Exceptions

There are no post-completion exceptions available.

#### 13.5 Information Messages

There are no information messages available.

#### 13.6 Questions

There are no questions available.

#### 13.7 Decisions

There are no decisions available.

#### 13.8 Error Messages (SR0527.3.6+)

Error messages are represented in an error message dialog containing a message type-specific icon, the error message, and an **OK** button.

The following error messages are available to inform the operator about error conditions.

- Set DCS Parameters Phase (SR0527+)
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### **13.8.1 Set DCS Parameter Value-specific Error Messages**

#### **13.8.1.1 GID-2670919 SET PARAMETER ERROR (SR0527.3.6.1)**

UI text	Comment
Setting of parameters failed.	Message pack: PhaseSetDCSParameters<version> Message ID: Set_Param_Error_message

The **Details** button provides access to more specific technical information.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

### **13.8.2 Phase Completion-specific Error Messages**

#### **13.8.2.1 GID-2670920 NO PARAMETERS SET (SR0527.3.6.2)**

UI text	Comment
You have to set DCS parameters before you can confirm.	Message pack: PhaseSetDCSParameters<version> Message ID: ParametersNotSet_ErrorMsg

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

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### **13.8.3 User-triggered Exception-specific Error Messages**

#### **13.8.3.1 GID-2670921 INVALID DATA FORMAT ERROR (SR0527.3.6.3)**

<b>UI text</b>	<b>Comment</b>
The value must be a duration. Please correct your input.	Message pack: PhaseSetDCSParameters<version> Message ID: OverrideDCSParameterDurationError_ErrorMsg  Potential error cause: The entered text value cannot be converted to a duration value of the targeted duration data type.
The value must be a number. Please correct your input.	Message pack: PhaseSetDCSParameters<version> Message ID: OverrideDCSParameterNumberError_ErrorMsg  Potential error cause: The entered text value cannot be converted to a numeric value of the targeted numeric data type.
The value must be a timestamp. Please correct your input.	Message pack: PhaseSetDCSParameters<version> Message ID: OverrideDCSParameterTimestampError_ErrorMsg  Potential error cause: The entered text value cannot be converted to a timestamp value of the targeted timestamp data type.

<b>Attribute</b>	<b>Value</b>
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

### 13.8.3.2 GID-2670922 NO VALUE OVERRIDDEN (SR0527.3.6.4)

UI text	Comment
Enter at least one new value.	Message pack: PhaseSetDCSParameters<version> Message ID: OverrideDefinitionParameterNoEntryError_ErrorMsg Potential error cause: No override value was entered before the user-triggered exception was confirmed.
Enter a new value.	Message pack: PhaseSetDCSParameters<version> Message ID: OverrideValueNotSet_ErrorMsg Potential error cause: No override value was entered before the user-triggered exception was confirmed.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

### 13.8.3.3 GID-3505049 RANGE VIOLATION ERROR

UI text	Comment
<entered value> is outside of the range of valid values. The value must not be lower than <lower limit> and higher than <upper limit>.	Message pack: PhaseDCSSetDCSParameters1101 Message ID: RangeViolation_ErrorMsg Potential error cause: The entered value is outside the range of valid values.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

## 13.9 Output Variables (SR0527.9+)

The following output variables are available to reference the phase's output.

### 13.9.1 Instance count (Framework capability)

- Data type: Long
- Usage: The output variable provides the count of the number of instances the phase has been processed, for example in a loop. The count is also increased when the phase is skipped from an operator's perspective, since the phase is still executed, but as a hidden phase.  
The count variable of a phase that has not been executed provides 0 as output value.

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### **13.9.2 Start time (Framework capability)**

- Data type: Timestamp
- Usage: The output variable provides the start time of the phase.

### **13.9.3 Completion time (Framework capability)**

- Data type: Timestamp
- Usage: The output variable provides the completion time of the phase.

### **13.9.4 Identifier (Framework capability)**

- Data type: String
- Usage: The output variable provides the identifier of the phase.

### **13.9.5 Boolean Value Bundle**

#### **13.9.5.1 [BOOLEAN] BUNDLE OUTPUT VARIABLE (FRAMEWORK CAPABILITY)**

For all output variables of the same bundle, the output variable identifier is a concatenation of the bundle identifier and the output variable name.

This framework capability refers to **Bundle Output Variable (SR3146.9.7.4.2)** in "Functional Requirement Specification Recipe and Workflow Management" [A4] ([GID-2667776](#))

#### **13.9.5.2 GID-2670924 [BOOLEAN] PARAMETER (SR0527.9.2)**

- Data type: String
- Usage: The output variable provides the identifier of the parameter that was used to set the DCS parameter values.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

#### **13.9.5.3 GID-2670925 [BOOLEAN] VALUE (SR0527.9.3)**

- Data type: Boolean
- Usage: The output variable provides the value of the parameter that was set on the DCS.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

### **13.9.6 Duration Value Bundle**

#### **13.9.6.1 [DURATION] BUNDLE OUTPUT VARIABLE (FRAMEWORK CAPABILITY)**

For all output variables of the same bundle, the output variable identifier is a concatenation of the bundle identifier and the output variable name.

This framework capability refers to **Bundle Output Variable (SR3146.9.7.4.2)** in "Functional Requirement Specification Recipe and Workflow Management" [A4] [\(GID-2667776\)](#)

#### **13.9.6.2 GID-2670927 [DURATION] PARAMETER (SR0527.9.4)**

- Data type: String
- Usage: The output variable provides the identifier of the parameter that was used to set the DCS parameter values.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

#### **13.9.6.3 GID-2670928 [DURATION] VALUE (SR0527.9.5)**

- Data type: Duration
- Usage: The output variable provides the value of the parameter that was set on the DCS.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

### **13.9.7 Numeric Value Bundle**

#### **13.9.7.1 [NUMERIC] BUNDLE OUTPUT VARIABLE (FRAMEWORK CAPABILITY)**

For all output variables of the same bundle, the output variable identifier is a concatenation of the bundle identifier and the output variable name.

This framework capability refers to **Bundle Output Variable (SR3146.9.7.4.2)** in "Functional Requirement Specification Recipe and Workflow Management" [A4] [\(GID-2667776\)](#)

#### **13.9.7.2 GID-2670930 [NUMERIC] PARAMETER (SR0527.9.6)**

- Data type: String
- Usage: The output variable provides the identifier of the parameter that was used to set the DCS parameter values.

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Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

### 13.9.7.3 GID-2670931 [NUMERIC] VALUE (SR0527.9.7)

- Data type: BigDecimal
- Usage: The output variable provides the value of the parameter that was set on the DCS.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

### 13.9.8 String Value Bundle

#### 13.9.8.1 [STRING] BUNDLE OUTPUT VARIABLE (FRAMEWORK CAPABILITY)

For all output variables of the same bundle, the output variable identifier is a concatenation of the bundle identifier and the output variable name.

This framework capability refers to **Bundle Output Variable (SR3146.9.7.4.2)** in "Functional Requirement Specification Recipe and Workflow Management" [A4] [\(GID-2667776\)](#)

#### 13.9.8.2 GID-2670933 [STRING] PARAMETER (SR0527.9.8)

- Data type: String
- Usage: The output variable provides the identifier of the parameter that was used to set the DCS parameter values.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

#### 13.9.8.3 GID-2670934 [STRING] VALUE (SR0527.9.9)

- Data type: String
- Usage: The output variable provides the value of the parameter that was set on the DCS.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

### 13.9.9 *Timestamp Value Bundle*

#### 13.9.9.1 [TIMESTAMP] BUNDLE OUTPUT VARIABLE (FRAMEWORK CAPABILITY)

For all output variables of the same bundle, the output variable identifier is a concatenation of the bundle identifier and the output variable name.

This framework capability refers to **Bundle Output Variable (SR3146.9.7.4.2)** in "Functional Requirement Specification Recipe and Workflow Management" [A4] ([GID-2667776](#))

#### 13.9.9.2 GID-2670936 [TIMESTAMP] PARAMETER (SR0527.9.10)

- Data type: String
- Usage: The output variable provides the identifier of the parameter that was used to set the DCS parameter values.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

#### 13.9.9.3 GID-2670937 [TIMESTAMP] VALUE (SR0527.9.11)

- Data type: Timestamp
- Usage: The output variable provides the value of the parameter that was set on the DCS.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

### 13.10 Configuration Keys (SR0527.11+)

The following configuration keys are available to configure the phase's behavior.

#### 13.10.1 GID-2669176 Message broker URL (SR0527.11.1)

- Phase/DCS/DCSMesssageBrokerURL
- **Type:** String
- **Value:** tcp://<hostname>:<port>
- **Description:** Specifies the URL of the messaging server used for DCS communication. Replace <hostname> with the name of the host to be used and <port> with the port number of the host to be used.  
If no value is set, the URL defined in the PharmaSuite **MessageBrokerURL** configuration key is used.
- **Evaluated:** When a DCS phase communicates with a DCS.

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- **Range:** N/A

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

### 13.10.2 *GID-2669177 Messaging timeout (SR0527.11.2)*

- Phase/DCS/DCSMessagingTimeout
- **Type:** Long
- Value: 2
- **Description:** The messaging timeout for DCS communication in seconds and the time how long a produced DCS message shall be retained by the messaging system after it has been dispatched.  
If no value is set, the timeout defined in the PharmaSuite **MessagingTimeout** configuration key is used (converted into seconds).
- **Evaluated:** When a DCS phase communicates with a DCS.
- **Range:** N/A

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

## 14 Reference Documents

The following documents are available from the Rockwell Automation Download Site.

No.	Document Title	Part Number
A1	FT PharmaSuite Functional Requirement Specification Execution Framework	PSFRSEF-RM007B-EN-E
A2	Functional Requirement Specification DCS Adapter	DCFRSAD-RM004A-EN-E
A3	Technical Guide DCS Adapter	DCTMAD-GR004A-EN-E
A4	FT PharmaSuite Functional Requirement Specification Recipe and Workflow Management	PSFRSRD-RM011B-EN-E
A5	FT PharmaSuite Functional Requirement Specification IPC Phases	PSFRSIP-RM006B-EN-E

**TIP**

To access the Rockwell Automation Download Site, you need to acquire a user account from Rockwell Automation Sales or Support.

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## 15 Document Information

The document information covers various data related to the document.

### 15.1 Approval

This document has been approved electronically via the Rockwell Automation Document Management System (DMS). The required approvers of this document include the following:

Name	Role
Norbert Ern	Product Owner
Sandesh Ghule	Technical Lead
Ignaz Wangler	Test Lead

### 15.2 Version Information

Object	Version
FT PharmaSuite	11.01.00
Create DCS Batch	11.0
Get DCS Alarms	11.0
DCS Alarm-based Trigger	11.0
Set Order Context	11.1
Show Consumed Material	11.1
Show Produced Material	11.0
Wait for Event (OES)	11.0
Wait for Event	11.0
Send Event	11.0

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Object	Version
Get DCS Parameters	11.1
Set DCS Parameters	11.1
Functional Requirement Specification	1.0

# 16 Appendix A - Revision History

## 16.1 Updated Requirements

- [GID-2670173](#) Instruction (SR0520.8.1)
- [GID-2670213](#) Active mode (SR0500.1.2)
- [GID-2670224](#) Instruction (SR0500.8.1)
- [GID-2670229](#) Retrieval exception (SR0500.8.5)
- [GID-2670230](#) Unconverted alarms (SR0500.8.6)
- [GID-2670239](#) Alarm exception (SR0500.3.1.1)
- [GID-2670240](#) Alarm exception - Logic (SR0500.3.1.1.1)
- [GID-2667692](#) Set Order Context Phase (SR0530+)
- [GID-2670276](#) Instruction (SR0530.8.1)
- [GID-2670279](#) Set order context manually (SR0530.8.4)
- [GID-2670280](#) Re-send order context (SR0530.8.5)
- [GID-2667703](#) Show Consumed Material Phase (SR0535+)
- [GID-2670667](#) Instruction (SR0535.8.1)
- [GID-2670669](#) Remove incorrectly recorded data set (SR0535.8.2)
- [GID-2670670](#) Add consumption (SR0535.8.3)
- [GID-2670678](#) Completed mode (SR0536.1.3)
- [GID-2670691](#) Instruction (SR0536.8.1)
- [GID-2668793](#) Messaging timeout (SR0536.11.2)
- [GID-2670714](#) Instruction (SR0545.8.3)
- [GID-2670731](#) Instruction (SR0550.8.1)
- [GID-2667754](#) Get DCS Parameters Phase (SR0526+)
- [GID-2670755](#) Instruction (SR0526.8.1)
- [GID-2670759](#) Override DCS parameter value (SR0526.8.4)
- [GID-2670767](#) [Boolean Extended] Bundle process parameters (Framework capability)
- [GID-2670772](#) [Duration] Bundle process parameters (Framework capability)
- [GID-2670780](#) [Duration Extended] Bundle process parameters (Framework capability)
- [GID-2670833](#) Limit violation (SR0526.3.2.1)

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[GID-2670836](#) Override DCS parameter value (SR0526.3.1.1)

[GID-2670837](#) Override DCS parameter value - Logic (SR0526.3.1.1.1)

[GID-2670840](#) Invalid data format error (SR0526.3.6.3)

[GID-2670841](#) No value overridden (SR0526.3.6.4)

[GID-2668875](#) Retrieval successful (SR0526.9.1)

[GID-2670844](#) [Boolean] Retrieval successful (SR0526.9.3)

[GID-2670853](#) [Duration Extended] Retrieval successful (SR0526.9.9)

[GID-3453909](#) [Numeric Extended] Bundle output variable (Framework capability)

[GID-2670859](#) [Numeric Extended] Retrieval successful (SR0526.9.13)

[GID-2670862](#) [String] Retrieval successful (SR0526.9.15)

[GID-2667765](#) Set DCS Parameters Phase (SR0527+)

[GID-2670888](#) Instruction (SR0527.8.1)

[GID-2670892](#) Re-send request (SR0527.8.5)

[GID-2670893](#) Set DCS parameters manually (SR0527.8.6)

[GID-2670894](#) Override bundle parameter (SR0527.8.7)

[GID-2670895](#) Override definition (SR0527.8.8)

[GID-2670915](#) Override bundle parameter (SR0527.3.1.3)

[GID-2670917](#) Override definition (SR0527.3.1.4)

[GID-2670918](#) Override definition - Logic (SR0527.3.1.4.1)

[GID-2670922](#) No value overridden (SR0527.3.6.4)

## 16.2 Added Requirements

[GID-3500023](#) Range violation error

[GID-3505049](#) Range violation error

## 16.3 Deleted Requirements

**None**

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